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| TOOTH.DWPI,TDBD,EPAB,JPAB,USPT. | 182848 |
| TEETH.DWPI,TDBD,EPAB,JPAB,USPT. | 248878 |
| DENTAL.DWPI,TDBD,EPAB,JPAB,USPT. | 63096 |
| (3 AND (DENTAL OR TOOTH OR TEETH)).USPT,JPAB,EPAB,DWPI,TDBD. | 19 |
| (L3 AND (TOOTH OR TEETH OR DENTAL)).USPT,JPAB,EPAB,DWPI,TDBD. | 19 |

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| <u>L10</u> | l3 and (tooth or teeth or dental) | 19 | <u>L10</u> |
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| <u>L8</u> | l3 and (compartment? or chambers? or dual or first and second) | 140 | <u>L8</u> |
| <u>L7</u> | l3 and silica.clm. | 12 | <u>L7</u> |
| <u>L6</u> | l3 and fumed silica | 5 | <u>L6</u> |
| <u>L5</u> | l3 and l4 | 8 | <u>L5</u> |
| <u>L4</u> | cabosil | 1042 | <u>L4</u> |
| <u>L3</u> | l1 and l2 | 221 | <u>L3</u> |
| <u>L2</u> | (peroxide.clm. or bleach?.clm. or whiten?.clm.) | 16096 | <u>L2</u> |
| <u>L1</u> | (hydroxypropylcellulose or hydroxypropylcellulose.clm. or klucel or klucel.clm.) | 9018 | <u>L1</u> |

END OF SEARCH HISTORY

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L10: Entry 8 of 19

File: USPT

Feb 17, 1998

DOCUMENT-IDENTIFIER: US 5718886 A

TITLE: Stabilized anhydrous tooth whitening gelAbstract Text (1):

Stabilized anhydrous dental whitening gel compositions are provided which resist viscosity degradation during oral use. An illustrative anhydrous dental bleaching gel composition embodying this feature comprises propylene glycol, polyethylene glycol, glycerin in an amount not exceeding about 10 wt. %, neutralized carboxypolymethylene, hydroxypropylcellulose, xanthan gum and carbamide peroxide.

Parent Case Text (2):

This application is a continuation-in-part of U.S. patent application Ser. No. 08/599,364 filed Mar. 11, 1996 now U.S. Pat. No. 5,631,000 and entitled Anhydrous Tooth Whitening Gel.

Brief Summary Text (2):

This invention relates to dental compositions and, more particularly, to stabilized anhydrous tooth whitening gel compositions, a method for preparing the gel compositions, and a method for utilizing the gel compositions.

Brief Summary Text (4):

In that aspect of aesthetic dentistry which relates to self-administered use of in-home tooth whitening compositions, the dental patient is provided with a custom-fitted dental tray having selectively enlarged tooth treating compartments which are adapted to receive a whitening gel that is dispensed from a syringe. The dental tray, with its gel content, is unobtrusively and advantageously worn by the patient at night and while the patient sleeps. This treatment is repeated for a sufficient period of time to effect the tooth bleaching and whitening process.

Brief Summary Text (5):

It is disclosed in the prior art that carboxypolymethylene as well as methylcellulose can be used as the gelation agents in the formulation of tooth whitening gels. The prior art also discloses that carbamide peroxide (urea peroxide) as well as hydrogen peroxide can be used as the whitening agents in the formulation of tooth whitening gels.

Brief Summary Text (6):

U.S. Pat. No. 5,290,566 (Schow, et al., 1994) discloses a tooth whitening gel containing urea peroxide (carbamide peroxide), methylcellulose and water wherein the concentration of urea peroxide is from about 22 to about 32 wt. %.

Brief Summary Text (7):

U.S. Pat. Nos. 5,098,303 (Fischer, 1992), 5,234,342 (Fischer, 1993), 5,376,006 (Fischer, 1994) and 5,409,631 (Fischer, 1995), which are incorporated herein by reference, disclose tooth bleaching and whitening gel compositions formulated with carbamide peroxide, water, glycerin, carboxypolymethylene and sodium hydroxide. With respect to broad range ingredient concentration, the formulations contain from about 3.0 to about 20 wt. % carbamide peroxide, from about 10 to about 60 wt. % water, from about 20 to about 70 wt. % glycerin, from about 3.5 to about 12 wt. % carboxypolymethylene and sodium hydroxide in an amount to substantially neutralize the carboxypolymethylene. The gel is characterized as comprising a saturated or super saturated carboxypolymethylene composition wherein the actual concentration of carboxypolymethylene in the total quantity of water in the gel composition is in the

range from about 15% to about 40%, with the concentrated carboxypolymethylene providing the gel composition with a tackiness or stickiness. As to gel preparation, the patentee recommends that the carboxypolymethylene be mixed with glycerin and the resulting admixture dispersed in water, followed by the addition of the remaining ingredients, namely, sodium hydroxide and carbamide peroxide.

Brief Summary Text (8):

It has been observed that carbamide peroxide tooth whitening gels containing relatively high concentrations of water, glycerin and carboxypolymethylene (a) tend to have limited package stability as a result of the interaction of carbamide peroxide with water, (b) tend to increase tooth sensitivity as a result of the hygroscopic properties of glycerin which can reduce the moisture level at the tooth treatment surface, and (c) tend to string from one tooth treating compartment in the bleaching tray to the next tooth treating compartment in the tray in the course of syringe loading the compartments with the bleaching gel.

Brief Summary Text (9):

Although the foregoing limitations have been addressed by the development and use of anhydrous tooth whitening gels, it has now been observed that tooth whitening gels formulated with thickeners such as carboxypolymethylene and/or cellulosics exemplified by carboxymethylcellulose, hydroxymethylcellulose and hydroxypropylcellulose tend to decrease in viscosity with an increase in temperature. During overnight oral application of the tooth whitening gel, the temperature of the gel in the dental tray can increase from ambient to about 37.degree. C. (98.6.degree. F.). As a result of this rise in temperature, the gel tends to thin and become somewhat flowable. If the gel gets too thin, it may flow out of the tray and into contact with the soft tissue, causing tissue irritation.

Brief Summary Text (11):

An important object of the present invention is to provide new and improved dental whitening compositions which address the viscosity limitations of the prior art tooth whitening gels as hereinabove described.

Brief Summary Text (12):

Another object of this invention is to provide tooth whitening gel compositions which enable a reduced concentration of carboxypolymethylene to be used as a thickener without impairing the requisite viscosity characteristics of the gel compositions during oral use.

Brief Summary Text (13):

A further object of this invention is to provide tooth whitening gel compositions which resist viscosity degradation during oral use.

Brief Summary Text (14):

An additional object of this invention is to provide tooth whitening gel compositions which retain their viscosity in the presence of an increase in temperature and a decrease in pH that are encountered during oral use.

Brief Summary Text (16):

In accordance with one aspect of this invention, there is provided a tooth whitening composition containing carbamide peroxide dispersed in a substantially anhydrous gelatinous carrier. The anhydrous carrier comprises a polyol component wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition. The anhydrous carrier also comprises a thickener component containing neutralized carboxypolymethylene, cellulolic ether soluble in the polyol component and a viscosity stabilizer comprising xanthan gum.

Brief Summary Text (17):

In accordance with a second aspect of this invention, there is provided a method for whitening teeth which comprises (1) extruding a substantially anhydrous tooth whitening gel composition into the reservoir system of a dental bleaching tray, (2) placing the dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened, (3) maintaining the gel composition in contact with the aforesaid teeth for a plurality of hours per day, and (4) repeating steps 1, 2 and 3 for multiple days to effect whitening of the teeth. The anhydrous

tooth whitening gel composition which can be used in carrying out the method advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 50 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 55 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %, (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %.

Brief Summary Text (18):

In accordance with a third aspect of this invention, there is provided a method for preparing substantially anhydrous dental whitening gel compositions. The method comprises admixing a settable ingredient mix to obtain a homogenous dispersion of the ingredients. The settable ingredient mix advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %, (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %, (i) wherein weight percent is based on the total weight of the gel composition.

Brief Summary Text (20):

The dental whitening gel compositions of this invention comprise carbamide peroxide dispersed in an anhydrous gelatinous carrier. Carbamide peroxide is generally present in the anhydrous gel compositions in an amount from about 5 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Brief Summary Text (22):

Glycerin can also be used as a constituent of the liquid component. However, glycerin is hygroscopic and a high concentration of glycerine in the gel tends to pull moisture away from the surface of the teeth which can lead to increased dental sensitivity to the bleaching composition. Accordingly, if glycerin is used in the bleaching gel, it should be limited to a concentration that does not exceed about 10 wt. % of the gel composition. In a more specific aspect, glycerin can be present in the gel composition in an amount from about 3.0 wt. % to about 9.0 wt. %.

Brief Summary Text (24):

Cellulosic ether is generally present in the gel compositions in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. %. A preferred cellulosic ether is hydroxypropylcellulose.

Brief Summary Text (25):

The blend of neutralized carboxypolymethylene and cellulosic ether is particularly advantageous because the blend provides the gel compositions with improved thixotropic properties in respect of flow-set characteristics. This rheological enhancement constitutes an improvement in the dental whitening art because it tends to minimize the stringing and roping of the gel from one tooth treating compartment to the next tooth treating compartment during the sequential syringe loading of the gel into the compartments of the dental whitening tray.

Brief Summary Text (27):

The anhydrous tooth whitening gels of this invention are prepared by adding and mixing the ingredients of the formulation in a suitable vessel such as a stainless steel tank that is provided with a heavy duty mixer which is suitable for use with thick gels. If desired, the mixing vessel can be combined with vacuum equipment for carrying out the admixing of the ingredients under vacuum conditions. The ingredients of the formulation are mixed to obtain a homogenous dispersion which sets to a thixotropic gel.

Brief Summary Text (28):

In the preparation of the dental whitening gels, the formulating ingredients are advantageously added to the mixing vessel in the following order: liquid ingredients, thickener ingredients, alkalinizing agent, carbamide peroxide, and any desired flavoring.

Brief Summary Text (29) :

The quantities of the formulating ingredients are so selected as to provide the whitening gels with a composition containing (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. % and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. % and, preferably, in an amount from about 3.0 wt. % to about 9.0 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. % and, preferably, in an amount from about 1.5 wt. % to about 2.5 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. % (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. % and, preferably, in an amount from about 0.3 wt. % to about 1.3 wt. %, (g) neutralizing reagent, preferably, anhydrous sodium hydroxide in an amount to substantially neutralize carboxypolymethylene, and (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Detailed Description Text (2) :

The following examples further illustrate the anhydrous tooth whitening gels of this invention and the concentration ranges for the ingredients thereof. As used in the examples, "PEG" is a trade designation for polyethylene glycol (Merck Index No. 7545, 11th ed.), "Carbopol" is a trademark for carboxypolymethylene (Merck Index No. 1836, 11th ed.) and "Klucel" is a trademark for hydroxypropylcellulose (Merck Index No. 4776, 11th ed.). The bleaching gels were prepared in accordance with the method and procedure as hereinabove described.

Detailed Description Text (3):

The anhydrous tooth whitening gel compositions, as hereinabove described, are packaged in appropriate syringes for dispensing into custom-fitted dental trays that are usually worn at night, but can also be worn during the day, with maximum whitening generally occurring when the treatment is continued for ten to fourteen days. The custom-fitted dental bleaching trays can be prepared by using materials and procedures that are well known in the dental art, and which are described in the prior art cited herein.

Detailed Description Text (4):

In a first alternative packaging embodiment, the dental whitening gels can be packaged in gel dispensing tubes or bottles for extrusion into general purpose dental trays for carrying out the dental whitening process. In a second alternative packaging embodiment, pre-packaged dental trays can be provided to the user containing dental whitening gels which have been adapted for this purpose.

Detailed Description Paragraph Table (1):

CLAIMS:

1. A tooth whitening gel composition comprising carbamide peroxide dispersed in an anhydrous gelatinous carrier, said carrier comprising:
 - (a) a polyol component wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition;
 - (b) a thickener component containing neutralized carboxypolymethylene and cellulosic either soluble in the polyol component; and
 - (c) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. % for stabilizing the gel composition against viscosity degradation during oral use.
6. The composition of claim 1 wherein the concentration of carbamide peroxide is from about 5.0 wt. % to about 25 wt. %.
7. An anhydrous tooth whitening gel composition comprising:
 - (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
 - (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
 - (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
 - (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
 - (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
 - (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %,
 - (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
 - (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %.
11. The composition of claim 7 wherein carboxypolymethylene is present in an amount from about 1.5 wt. % to about 2.5 wt. % and hydroxypropylcellulose is present in an amount from about 1.0 wt. % to about 3.0 wt. %.
12. The composition of claim 7 wherein carbamide peroxide is present in an amount from about 10 wt. % to about 20 wt. %.
13. A method for whitening teeth which comprises:
 - (1) extruding an anhydrous teeth whitening gel composition into the reservoir system of a teeth bleaching dental tray, said gel composition comprising:
 - (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
 - (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
 - (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
 - (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
 - (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
 - (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %,
 - (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and

- (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %;
- (2) placing said dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened;
- (3) maintaining said gel composition in contact with said teeth for a plurality of hours per day; and
- (4) repeating steps 1, 2 and 3 for multiple days to thereby whiten the teeth.

15. The method of claim 13 wherein glycerin is present in the gel composition in an amount from about 3.0 wt. % to about 9.0 wt. %; carboxypolymethylene is present in the gel composition in an amount from about 1.5 wt. % to about 2.5 wt. %; and hydroxypropylcellulose is present in the gel composition in an amount from about 1.0 wt. % to about 3.0 wt. %.

16. A method for preparing an anhydrous tooth whitening gel composition, which method comprises admixing:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %,
- (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %,
- (i) wherein weight percent is based on the total weight of the gel composition.

17. The method of claim 16 wherein the amount of glycerin is from about 3.0 wt. % to about 9.0 wt. %, the amount of carboxypolymethylene is from about 1.5 wt. % to about 2.5 wt. %, the amount of hydroxypropylcellulose is from about 1.0 wt. % to about 3.0 wt. %, and the amount of xanthan gum is from about 0.3 wt. % to about 1.3 wt. %.

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L10: Entry 10 of 19

File: USPT

May 20, 1997

DOCUMENT-IDENTIFIER: US 5631000 A
TITLE: Anhydrous tooth whitening gel

Abstract Text (1):

An anhydrous dental bleaching gel composition is provided which has improved package stability, improved rheology and reduced sensitivity during use. An illustrative anhydrous dental bleaching gel composition embodying these features comprises propylene glycol, polyethylene glycol, glycerin in an amount not exceeding about 10 wt. %, neutralized carboxypolymethylene, hydroxypropylcellulose, and carbamide peroxide.

Brief Summary Text (2):

This invention relates to dental compositions and, more particularly, to anhydrous tooth whitening gel compositions, a method for preparing the gel compositions, and a method for utilizing the gel compositions.

Brief Summary Text (4):

In that aspect of aesthetic dentistry which relates to self-administered use of in-home tooth whitening compositions, the dental patient is provided with a custom-fitted dental tray having selectively enlarged tooth treating compartments which are adapted to receive a whitening gel that is dispensed from a syringe. The dental tray, with its gel content, is unobtrusively and advantageously worn by the patient at night and while the patient sleeps. This treatment is repeated for a sufficient period of time to effect the tooth bleaching and whitening process.

Brief Summary Text (5):

It is disclosed in the prior art that carboxypolymethylene as well as methylcellulose can be used as the gelation agents in the formulation of tooth whitening gels. The prior art also discloses that carbamide peroxide (urea peroxide) as well as hydrogen peroxide can be used as the whitening agents in the formulation of tooth whitening gels.

Brief Summary Text (6):

U.S. Pat. No. 5,290,566 (Schow, et al., 1994) discloses a tooth whitening gel containing urea peroxide (carbamide peroxide), methylcellulose and water wherein the concentration of urea peroxide is from about 22 to about 32 wt. %.

Brief Summary Text (7):

U.S. Pat. No. 5,098,303 (Fischer, 1992), U.S. Pat. No. 5,234,342 (Fischer, 1993), U.S. Pat. No. 5,376,006 (Fischer, 1994) and U.S. Pat. No. 5,409,631 (Fischer, 1995), which are incorporated herein by reference, disclose tooth bleaching and whitening gel compositions formulated with carbamide peroxide, water, glycerin, carboxypolymethylene and sodium hydroxide. With respect to broad range ingredient concentration, the formulations contain from about 3.0 to about 20 wt. % carbamide peroxide, from about 10 to about 60 wt. % water, from about 20 to about 70 wt. % glycerin, from about 3.5 to about 12 wt. % carboxypolymethylene and sodium hydroxide in an amount to substantially neutralize the carboxypolymethylene. The gel is characterized as comprising a saturated or super saturated carboxypolymethylene composition wherein the actual concentration of carboxypolymethylene in the total quantity of water in the gel composition is in the range from about 15% to about 40%, with the concentrated carboxypolymethylene providing the gel composition with a tackiness or stickiness. As to gel preparation, the patentee recommends that the carboxypolymethylene be mixed with glycerin and the resulting admixture dispersed in

water, followed by the addition of the remaining ingredients, namely, sodium hydroxide and carbamide peroxide.

Brief Summary Text (8):

It has been observed that carbamide peroxide tooth whitening gels containing relatively high concentrations of water, glycerin and carboxypolymethylene (a) tend to have limited package stability as a result of the interaction of carbamide peroxide with water, (b) tend to increase tooth sensitivity as a result of the hygroscopic properties of glycerin which can reduce the moisture level at the tooth treatment surface, and (c) tend to string from one tooth treating compartment in the bleaching tray to the next tooth treating compartment in the tray in the course of syringe loading the compartments with the bleaching gel.

Brief Summary Text (10):

An important object of the present invention is to provide new and improved dental whitening compositions which address the limitations of the prior art dental bleaching gels as hereinabove described.

Brief Summary Text (11):

Another object of this invention is to provide dental whitening compositions which have improved package stability with respect to the active bleaching agent, namely, the peroxide constituent.

Brief Summary Text (12):

A further object of this invention is to provide dental whitening compositions which have reduced sensitivity during use.

Brief Summary Text (13):

An additional object of this invention is to provide dental whitening compositions which have improved thixotropic properties with respect to flow-set characteristics.

Brief Summary Text (15):

In accordance with one aspect of this invention, there is provided a dental whitening composition containing carbamide peroxide dispersed in a substantially anhydrous gelatinous carrier. The anhydrous carrier comprises a liquid component wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition. The anhydrous carrier also comprises a thickener component containing neutralized carboxypolymethylene and cellulosic ether soluble in the liquid component.

Brief Summary Text (16):

In accordance with a second aspect of this invention, there is provided a method for whitening teeth which comprises (1) extruding a substantially anhydrous dental bleaching gel composition into the reservoir system of a dental bleaching tray, (2) placing the dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened, (3) maintaining the gel composition in contact with the aforesaid teeth for a plurality of hours per day, and (4) repeating steps 1, 2 and 3 for multiple days to effect whitening of the teeth. The anhydrous dental bleaching gel composition which can be used in carrying out the method advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 50 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 55 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %.

Brief Summary Text (17):

In accordance with a third aspect of this invention, there is provided a method for preparing substantially anhydrous dental whitening gel compositions. The method comprises admixing a settable ingredient mix to obtain a homogenous dispersion of the ingredients. The settable ingredient mix advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %, (b) polyethylene glycol

in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. % (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %, (h) wherein weight percent is based on the total weight of the gel composition.

Brief Summary Text (19):

The dental whitening gel compositions of this invention comprise carbamide peroxide dispersed in an anhydrous gelatinous carrier. Carbamide peroxide is generally present in the anhydrous gel compositions in an amount from about 5 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Brief Summary Text (21):

Glycerin can also be used as a constituent of the liquid component. However, glycerin is hygroscopic and a high concentration of glycerine in the gel tends to pull moisture away from the surface of the teeth which can lead to increased dental sensitivity to the bleaching composition. Accordingly, if glycerin is used in the bleaching gel, it should be limited to a concentration that does not exceed about 10 wt. % of the gel composition. In a more specific aspect, glycerin can be present in the gel composition in an amount from about 3.0 wt. % to about 9.0 wt. %.

Brief Summary Text (23):

Cellulosic ether is generally present in the gel compositions in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. %. A preferred cellulosic ether is hydroxypropylcellulose.

Brief Summary Text (24):

The blend of neutralized carboxypolymethylene and cellulosic ether is particularly advantageous because the blend provides the gel compositions with improved thixotropic properties in respect of flow-set characteristics. This rheological enhancement constitutes an improvement in the dental bleaching art because it tends to minimize the stringing and roping of the gel from one tooth treating compartment to the next tooth treating compartment during the sequential syringe loading of the gel into the compartments of the dental bleaching tray.

Brief Summary Text (25):

The anhydrous dental bleaching gels of this invention are prepared by adding and mixing the ingredients of the formulation in a suitable vessel such as a stainless steel tank that is provided with a heavy duty mixer which is suitable for use with thick gels. If desired, the mixing vessel can be combined with vacuum equipment for carrying out the admixing of the ingredients under vacuum conditions. The ingredients of the formulation are mixed to obtain a homogenous dispersion which sets to a thixotropic gel.

Brief Summary Text (26):

In the preparation of the dental whitening gels, the formulating ingredients are advantageously added to the mixing vessel in the following order: liquid ingredients, thickener ingredients, alkalinizing agent, carbamide peroxide, and any desired flavoring.

Brief Summary Text (27):

The quantities of the formulating ingredients are so selective as to provide the whitening gels with a composition containing (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. % and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. % and, preferably, in an amount from about 3.0 wt. % to about 9.0 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. % and, preferably, in an amount from about 1.5 wt. % to about 2.5 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. %, (f)

neutralizing reagent, preferably, anhydrous sodium hydroxide in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Detailed Description Text (2):

The following examples further illustrate the anhydrous dental bleaching gels of this invention and the concentration ranges for the ingredients thereof. As used in the examples, "PEG" is a trade designation for polyethylene glycol (Merck Index No. 7545, 11th ed.), "Carbopol" is a trademark for carboxypolymethylene (Merck Index No. 1836, 11th ed.) and "Klucel" is a trademark for hydroxypropylcellulose (Merck Index No. 4776, 11th ed.). The bleaching gels were prepared in accordance with the method and procedure as hereinabove described.

Detailed Description Text (3):

The anhydrous dental whitening gel compositions, as hereinabove described, are packaged in appropriate syringes for dispensing into custom-fitted dental trays that are usually worn at night, but can also be worn during the day, with maximum whitening generally occurring when the treatment is continued for ten to fourteen days. The custom-fitted dental bleaching trays can be prepared by using materials and procedures that are well known in the dental art, and which are described in the prior art cited herein.

Detailed Description Text (4):

In a first alternative packaging embodiment, the dental whitening gels can be packaged in gel dispensing tubes or bottles for extrusion into general purpose dental trays for carrying out the dental whitening process. In a second alternative packaging embodiment, pre-packaged dental trays can be provided to the user containing dental whitening gels which have been adapted for this purpose.

Detailed Description Paragraph Table (1):

| | | Weight Percent Ingredients | Ex. 1 | Ex. 2 | Ex. 3 |
|-----------|-------|----------------------------|-------|------------|--------------------|
| Ex. 4 | Ex. 5 | Propylene glycol | 47.4 | 49.0 | 45.4 |
| 43.4 | 48.4 | PEG 600 | 20.0 | 21.7 | -- |
| | | 16.0 | 15.0 | PEG 1000 | 10.0 |
| | | | 11.7 | -- | 15.0 |
| | | | | PEG 1450 | -- |
| -- | 26.0 | 6.0 | -- | PEG 1500 | -- |
| | | -- | -- | -- | -- |
| | | Glycerin | 8.0 | 8.0 | 8.0 |
| | | | 8.0 | 7.0 | Carbopol 980 |
| 2.2 | 2.2 | 2.2 | 2.2 | Klucel GFF | 1.8 |
| | | | | 1.8 | 1.8 |
| | | | | 1.8 | Flavor |
| | | | | 0.2 | 0.2 |
| | | | | 0.2 | 0.2 |
| | | | | 0.2 | Sodium |
| | | | | 0.2 | hydroxide |
| hydroxide | 0.4 | 0.4 | 0.4 | 0.4 | Carbamide peroxide |
| 0.4 | 0.4 | 0.4 | 0.4 | 10.0 | 16.0 |
| 100.0 | 100.0 | 100.0 | 100.0 | 22.0 | 10.0 |
| 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 |

Detailed Description Paragraph Table (2):

| | | Weight Percent Ingredients | Ex. 6 | Ex. 7 | Ex. 8 |
|---------|------------|----------------------------|--------|------------------|--------------|
| Ex. 9 | | Propylene glycol | 46.4 | 45.4 | 54.2 |
| PEG 600 | -- | 28.0 | -- | PEG 1000 | 31.0 |
| | -- | PEG 1450 | -- | 16.0 | -- |
| -- | -- | PEG 1500 | -- | -- | -- |
| -- | 35.2 | Glycerin | 8.0 | 8.0 | 0.4 |
| | | | 3.0 | 3.0 | Carbopol 980 |
| | | | | 2.2 | 2.2 |
| | | | | 2.0 | 3.0 |
| | | | | Klucel GFF | 1.8 |
| 1.0 | Klucel MFF | -- | 0.8 | -- | 1.8 |
| | | | Flavor | 0.2 | 0.4 |
| | | | | 0.2 | 0.4 |
| | | | | 0.2 | 0.5 |
| | | | | Sodium hydroxide | 0.4 |
| | | | | 0.4 | 0.4 |
| | | | | 10.0 | 0.4 |
| | | | | 100.0 | 100.0 |
| | | | | 100.0 | 100.0 |
| | | | | 100.0 | 100.0 |

CLAIMS:

1. An anhydrous tooth whitening gel composition comprising carbamide peroxide dispersed in an anhydrous gelatinous carrier, said carrier comprising:

(a) a liquid polyol wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition; and

(b) a thickener component containing neutralized carboxypolymethylene and cellulosic ether soluble in the liquid component,

said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

5. The composition of claim 1 wherein the concentration of carbamide peroxide is from about 5.0 wt. % to about 25 wt. %.

6. An anhydrous tooth whitening gel composition comprising:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %,

said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

11. The composition of claim 6 wherein hydroxypropylcellulose is present in an amount from about 1.0 wt. % to about 3.0 wt. %.

12. The composition of claim 6 wherein carbamide peroxide is present in an amount from about 10 wt. % to about 20 wt. %.

13. A method for whitening teeth which comprises:

(1) extruding an anhydrous tooth whitening gel composition into the reservoir system of a tooth bleaching dental tray, said gel composition comprising:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %;

(2) placing said dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened;

(3) maintaining said gel composition in contact with said teeth for a plurality of hours per day; and

(4) repeating steps 1, 2 and 3 for multiple days to thereby whiten the teeth,
said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

16. The method of claim 13 wherein hydroxypropylcellulose is present in the gel composition in an amount from about 1.0 wt. % to about 3.0 wt. %.

17. A method for preparing an anhydrous tooth whitening gel composition, which method comprises admixing:

(a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
(b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %,
(c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
(d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
(e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
(f) neutralizing reagent in an amount to substantially neutralize
carboxypolymethylene, and
(g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %,
(h) wherein weight percent is based on the total weight of the gel composition,
said anhydrous tooth whitening gel composition having enhanced package stability,
reduced tooth sensitivity, and improved thixotropic properties.

19. The method of claim 17 wherein the amount of carboxypolymethylene is from about 1.5 wt. % to about 2.5 wt. % and the amount of hydroxypropylcellulose is from about 1.0 wt. % to about 3.0 wt. %.

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| <u>L5</u> | l3 and l4 | 8 | <u>L5</u> |
| <u>L4</u> | cabosil | 1042 | <u>L4</u> |
| <u>L3</u> | l1 and l2 | 221 | <u>L3</u> |
| <u>L2</u> | (peroxide.clm. or bleach?.clm. or whiten?.clm.) | 16096 | <u>L2</u> |
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| COMPARTMENTA.DWPI,TDBD,EPAB,JPAB,USPT. | 1 |
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| COMPARTMENTP.DWPI,TDBD,EPAB,JPAB,USPT. | 1 |
| COMPARTMENTS.DWPI,TDBD,EPAB,JPAB,USPT. | 98341 |
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| <u>L6</u> | I3 and fumed silica | 5 | <u>L6</u> |
| <u>L5</u> | I3 and I4 | 8 | <u>L5</u> |
| <u>L4</u> | cabosil | 1042 | <u>L4</u> |
| <u>L3</u> | I1 and I2 | 221 | <u>L3</u> |
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| <u>L3</u> | l1 and l2 | 221 | <u>L3</u> |
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| <u>L7</u> | l3 and silica.clm. | 12 | <u>L7</u> |
| <u>L6</u> | l3 and fumed silica | 5 | <u>L6</u> |
| <u>L5</u> | l3 and l4 | 8 | <u>L5</u> |
| <u>L4</u> | cabosil | 1042 | <u>L4</u> |
| <u>L3</u> | l1 and l2 | 221 | <u>L3</u> |
| <u>L2</u> | (peroxide.clm. or bleach?.clm. or whiten?.clm.) | 16096 | <u>L2</u> |
| <u>L1</u> | (hydroxypropylcellulose or hydroxypropylcellulose.clm. or klucel or klucel.clm.) | 9018 | <u>L1</u> |

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| <u>L6</u> | l3 and fumed silica | 5 | <u>L6</u> |
| <u>L5</u> | l3 and l4 | 8 | <u>L5</u> |
| <u>L4</u> | cabosil | 1042 | <u>L4</u> |
| <u>L3</u> | l1 and l2 | 221 | <u>L3</u> |
| <u>L2</u> | (peroxide.clm. or bleach?.clm. or whiten?.clm.) | 16096 | <u>L2</u> |
| <u>L1</u> | (hydroxypropylcellulose or hydroxypropylcellulose.clm. or klucel or klucel.clm.) | 9018 | <u>L1</u> |

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L6: Entry 1 of 5

File: USPT

Apr 24, 2001

DOCUMENT-IDENTIFIER: US 6221341 B1
TITLE: Tooth whitening compositions

Brief Summary Text (41):

A thickener may also be added to increase contact time of either the single or multi-component composition on the tooth surface. This is particularly useful in tooth whitening methods where a dental tray is used to confine the material to a patient's dentition. Thickeners such as neutralized carboxypolyethylene and other polyacrylic acid polymers and copolymers, hydroxypropylcellulose and other cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), poly(vinylpyrrolidone), poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, stearic acid esters, and others are found to have utility in the formulation of tooth whitening compositions. The level of thickener, when present, is highly dependent upon the type chosen, but in general is included in the composition at a concentration of from about 0.5 percent by weight to about 20.0 percent by weight of the composition. It is to be understood that additional useful thickeners will become apparent to those skilled in the art based upon the disclosure herein.

Detailed Description Text (29):

The above composition was prepared by placing the polyethylene glycol into the mixing chamber, adding the sodium saccharin and glycetyl triacetate, and allowing to mix under vacuum at high speed until a clear solution was obtained. The polyvinylpyrrolidone was then added and mixed under vacuum at high speed until homogeneously dispersed. The fumed silica was then added, with slow mixing, to the above phase in the mixing chamber. The addition of the fumed silica resulted in a high degree of thickening of the total mixture. Finally, after the complete homogenization of the above dispersion (the thickened carrier matrix), the sodium percarbonate powder was added and dispersed thoroughly, again under vacuum and high speed mixing. Finally, the flavor was added and completely blended into the mixture. The resulting bleaching composition was a slightly off-white gel. The composition was transferred to polypropylene syringes for storage and testing.

Detailed Description Paragraph Table (7):

| | | | |
|----------------------------------|----------------------------|---------------------------|---------------------------------|
| TABLE 4 Ingredient Percent (w/w) | Polyethylene glycol 400 | 67.40 | Sodium saccharin 0.50 |
| Glycetyl triacetate 1.50 | Polyvinylpyrrolidone 10.00 | <u>Fumed silica</u> 12.00 | Sodium percarbonate powder 8.00 |
| Flavor 0.60 | TOTAL 100.00 | | |

Detailed Description Paragraph Table (8):

| | | | | | | | | | | | | | |
|----------------------------|--------------|---------------------------|-------------------------|--|-----------------------------------|------------------------|--------|--------------------|--------------------------|---------------------------------|-------------------------------------|-----------------------|------|
| TABLE 5 Percent (w/w) | A | B | B | C | Ingredient 1 | 2 | 1 | 2 | 1 | 2 | Propylene glycol 42.56 | 45.00 | |
| Polyethylene glycol 400 | 70.00 | 73.40 | Polyethylene glycol 600 | 23.00 | 33.90 | Glycerin 5.00 | 5.00 | 5.00 | Distilled water 2.67 | 69.24 | 82.80 | Sodium saccharin 0.80 | 0.80 |
| Potassium acesulfame 1.00 | Dequest 2010 | 0.10 | 0.40 | Sodium stannate 0.02 | Flavor 0.80 | 1.00 | 1.20 | Carbopol 974P 2.00 | 2.00 | 5.00 | <u>Hydroxypropylcellulose</u> 10.00 | 10.00 | |
| Polyvinylpyrrolidone 10.00 | 10.00 | <u>Fumed silica</u> 12.00 | 12.00 | Poly(vinylpyrrolidone-co-vinyl acetate) 1.00 | Sodium hydroxide monohydrate 2.67 | Ammonium hydroxide 29% | 3.20 | 3.20 | Carbamide peroxide 12.00 | Sodium percarbonate powder 8.00 | Hydrogen peroxide 35% | 17.14 | |
| Glycetyl triacetate 2.50 | 2.00 | 1.60 | TOTAL 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | 100.00 | |

CLAIMS:

1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

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L9: Entry 3 of 15

File: USPT

Apr 24, 2001

DOCUMENT-IDENTIFIER: US 6221341 B1
TITLE: Tooth whitening compositions

Abstract Text (1):

Novel compositions and methods are disclosed for cosmetically treating teeth in a manner to increase brightness or shade of the teeth. The compositions include a low molecular weight compound having a high acetyl group functionality useful in the production of a peroxy acid which then acts as a whitening agent.

Brief Summary Text (3):

Embodiments of the present invention relate in general to oral compositions, and more particularly, to tooth whitening compositions.

Brief Summary Text (5):

White teeth have long been considered cosmetically desirable. Unfortunately, due to the presence of chromogenic (color-causing) substances in food, beverages, tobacco, and salivary fluid, in addition to internal sources such as blood, amalgam restoratives, and antibiotics such as tetracycline, teeth become almost invariably discolored in the absence of intervention. The tooth structures that are generally responsible for presenting a stained appearance are enamel, dentin, and the acquired pellicle. Tooth enamel is predominantly formed from inorganic material, mostly in the form of hydroxyapatite crystals, and further contains approximately 5% organic material primarily in the form of collagen. In contrast, dentin is composed of about 20% protein including collagen, the balance consisting of inorganic material, predominantly hydroxyapatite crystals, similar to that found in enamel. The acquired pellicle is a proteinaceous layer on the surface of tooth enamel which reforms rapidly after an intensive tooth cleaning.

Brief Summary Text (6):

Staining of teeth results from extrinsic and/or intrinsic staining. Extrinsic staining of the acquired pellicle arises as a result of compounds such as tannins and other polyphenolic compounds which become trapped in and tightly bound to the proteinaceous layer on the surface of teeth. This type of staining can usually be removed by mechanical methods of tooth cleaning. In contrast, intrinsic staining occurs when staining compounds penetrate the enamel and even the dentin, or alternatively arise from sources within the tooth. This type of staining is not amenable to mechanical methods of tooth cleaning and chemical methods, which can penetrate into the tooth structure, are required. Intrinsic tooth staining is generally more intractable and difficult to remove than extrinsic tooth staining.

Brief Summary Text (7):

Consequently, tooth bleaching compositions generally fall into two categories: (1) gels, pastes, or liquids, including toothpastes that are mechanically agitated at the stained tooth surface in order to affect tooth stain removal through abrasive erosion of stained acquired pellicle; and (2) gels, pastes, or liquids that accomplish the tooth-bleaching effect by a chemical process while in contact with the stained tooth surface for a specified period, after which the formulation is removed. In some cases, an auxiliary chemical process, which may be oxidative or enzymatic, supplements the mechanical process.

Brief Summary Text (8):

Among the chemical strategies available for removing or destroying tooth stains, the most effective compositions contain an oxidizing agent, such as hydrogen peroxide,

in order to attack the chromogen molecules in such a way as to render them colorless, water-soluble, or both. In one of the most popular approaches to whitening a patient's teeth, a dental professional will construct a custom made dental bleaching tray for the patient from an impression made of the patient's dentition and prescribe the use of an oxidizing gel to be dispensed into the bleaching tray and worn intermittently for a period of from about 2 weeks to about 6 months, depending upon the severity of tooth staining. These oxidizing compositions, usually packaged in small plastic syringes or tubes, are dispensed directly by the patient into the custom-made tooth-bleaching tray, held in place in the mouth for contact times of greater than about 60 minutes, and sometimes as long as 8 to 12 hours. The slow rate of bleaching is in large part the consequence of the very nature of formulations that are developed to maintain stability of the oxidizing composition. The most commonly used oxidative compositions contain the hydrogen peroxide precursor carbamide peroxide which is mixed with an anhydrous or low-water content, hygroscopic viscous carrier containing glycerin and/or propylene glycol and/or polyethylene glycol. When contacted by water, carbamide peroxide dissociates into urea and hydrogen peroxide. Associated with the slow rate of bleaching in the hygroscopic carrier, the currently available tooth-bleaching compositions cause tooth sensitization in over 50% of patients. Tooth sensitivity is believed to result from the movement of fluid through the dentinal tubules, which is sensed by nerve endings in the tooth. The carriers for the carbamide peroxide enhance this movement. In fact, it has been determined that glycerin, propylene glycol and polyethylene glycol can each give rise to varying amounts of tooth sensitivity following exposure of the teeth to heat, cold, overly sweet substances, and other causative agents.

Brief Summary Text (9):

Prolonged exposure of teeth to bleaching compositions, as practiced at present, has a number of adverse effects in addition to that of tooth sensitivity. These include: solubilization of calcium from the enamel layer at a pH less than 5.5 with associated demineralization; penetration of the intact enamel and dentin by the bleaching agents, so as to reach the pulp chamber of a vital tooth thereby risking damage to pulpal tissue; and dilution of the bleaching compositions with saliva resulting in leaching from the dental tray and subsequent ingestion.

Brief Summary Text (10):

Alternatively, there are oxidizing compositions (generally those with relatively high concentrations of oxidizers) which are applied directly to the tooth surface of a patient in a dental office setting under the supervision of a dentist or dental hygienist. Theoretically, such tooth whitening strategies have the advantage of yielding faster results and better overall patient satisfaction; however, due to the high concentration of oxidizing agents contained in these so called "in-office" compositions, they can be hazardous to the patient and practitioner alike if not handled with care. The patient's soft tissues (the gingiva, lips, and other mucosal surfaces) must first be isolated from potential exposure to the active oxidizing agent by the use of a perforated rubber sheet (known as a rubber dam), through which only the teeth protrude. Alternatively, the soft tissue may be isolated from the oxidizers to be used in the whitening process by covering said soft tissue with a polymerizable composition that is shaped to conform to the gingival contours and subsequently cured by exposure to a high intensity light source. Once the soft tissue has been isolated and protected, the practitioner may apply the oxidizing agent directly onto the stained tooth surfaces for a specified period of time or until a sufficient change in tooth color has occurred. Typical results obtained through the use of a in-office tooth whitener, with or without activation by heat, range from about 2 to 3 shades (as measured with the VITA Shade Guide, VITA Zahnfarbk).

Brief Summary Text (11):

The range of tooth shades in the VITA Shade Guide varies from very light (B1) to very dark (C4). A total of 16 tooth shades constitute the entire range of colors between these two endpoints on a scale of brightness. Patient satisfaction with a tooth whitening procedure increases with the number of tooth shade changes achieved, with a generally accepted minimum change desirable of about 4 to 5 VITA shades.

Brief Summary Text (12):

Of the many peroxides available to the formulator of tooth whitening compositions,

hydrogen peroxide (and its adducts or association complexes, such as carbamide peroxide and sodium percarbonate) has been used almost exclusively. The chemistry of hydrogen peroxide is well known, although the specific nature of its interactions with tooth chromogens is poorly understood. It is believed that hydrogen peroxide destroys tooth chromogens in a similar fashion to that observed in the destruction of laundry stains, that is, by oxidizing unsaturated carbon-carbon, carbon-oxygen, and carbon-nitrogen bonds found in the stain molecules. A related class of compound, the peroxyacids, has been used in laundry detergents to effectively whiten clothes, due primarily to their stability in solution and their specific binding abilities to certain types of stain molecules. A number of stable, solid peroxyacids have been used, including diperoxydodecanoic acid and the magnesium salt of monoperoxyphthalic acid. Other peroxyacids, such as peroxyacetic acid, are available as solutions containing an equilibrium distribution of acetic acid, hydrogen peroxide, peroxyacetic acid and water. Alternatively, a peroxide donor such as sodium perborate or sodium percarbonate is formulated into a dry laundry detergent, together with a peroxyacid precursor. Upon contact with the wash water, the peroxide donor releases hydrogen peroxide into the wash solution, which then reacts with the peroxyacid precursor to form the actual peroxyacid. Examples of peroxyacids created in situ include peroxyacetic acid (from hydrogen peroxide and tetraacetylenediamine) and peroxybenzoic acid (from hydrogen peroxide and nonanoyloxybenzene sulfonate).

Brief Summary Text (14):

Peroxyacids have been used in oral care compositions to whiten stained teeth. U.S. Pat. No. 5,279,816 discloses a method of whitening teeth comprising the application of a peroxyacetic acid-containing composition having an acid pH. EP 545,594 A1 discloses the use of peroxyacetic acid in preparing a composition for whitening teeth. The peroxyacetic acid may be present in the composition, or in the alternative, may be generated in situ by combining a peroxide source with a peroxyacetic acid precursor during use. U.S. Pat. No. 5,302,375 discloses a composition that generates peroxyacetic acid within a vehicle in situ by combining water, acetylsalicylic acid and a water soluble alkali metal percarbonate.

Brief Summary Text (16):

Embodiments of the present invention are directed to compositions and methods useful in cosmetically treating teeth in a manner to improve the brightness or shade of the teeth. Embodiments of the present invention are also directed to compositions having antimicrobial activity for use in the therapeutic treatment of teeth. According to one embodiment of the present invention, a method is described whereby a composition is provided which upon contact with an aqueous medium or environment generates peroxyacetic acid for use as an oxidant in the tooth-whitening or stain removal process. Embodiments of the present method invention advantageously utilize compounds capable of generating peroxyacids quickly and effectively for application to teeth as compared to prior art compounds.

Brief Summary Text (18):

According to one embodiment of the present invention, the acyl group source is an acetyl group source being a low molecular weight molecule having at least one acetyl group to be used in the formation of a peroxy acid. According to this embodiment, the acetyl group source has a molecular weight and steric configuration that allows the acetyl group source to penetrate pores present in teeth after application of the acetyl group source. Once the acetyl group source has penetrated a tooth, a peroxide source can then be used to generate a peroxyacid within a tooth rather than only on the surface of the tooth. More efficient and greater whitening capabilities are achieved by using such acetyl group sources capable of penetrating pores in teeth.

Brief Summary Text (19):

According to a specific embodiment of the present invention, the acetyl group source is a low molecular weight C_{sub.1} -C_{sub.5} molecule having between 1 and 5 labile acetyl groups. In a acetyl groups. It is to be understood that labile functional groups having similar properties to acetyl groups are considered to be within the scope of the present invention, i.e. all that is required is that the active group be capable of forming an agent useful in the whitening or stain removal of teeth, such as a peroxyacid. Such labile functional groups include C_{sub.1} -C_{sub.5} acyl containing groups.

Brief Summary Text (20):

According to one embodiment of the present invention, the composition includes at least two components: one component including a source of peroxide (such as hydrogen peroxide), and a second component including a source of acetyl groups. The two components may be mixed together prior to application of the resulting mixture to the tooth surface. Alternatively, each component may be sequentially applied directly to the tooth surface. It should be noted that either of the components may be applied first before the application of the remaining component.

Brief Summary Text (21):

One object of the present invention, therefore, is to provide a novel composition which quickly and effectively produces a peroxyacid in an amount sufficient to whiten teeth. Another object of the present invention is to provide a method whereby a peroxyacid generating species is allowed to penetrate into the tooth and beyond the tooth surface where staining compounds may be present and then generating a peroxyacid or other tooth-whitening species within the tooth to provide a greater tooth whitening effect.

Brief Summary Text (24):

The principles of the present invention may be applied with particular advantage to obtain compositions and methods for the whitening or stain removal of teeth. The present invention, in one embodiment, is directed to a composition that whitens the color of teeth when applied to a stained tooth surface. The composition may be provided as a multi-component formulation including a peroxide source and a source of acetyl or functionally similar groups, which when combined produces an active ingredient useful in teeth whitening, such as a peroxyacid. According to one embodiment, the peroxide source is hydrogen peroxide or a hydrogen peroxide precursor and the source of acetyl or functionally similar groups is a C.sub.1 -C.sub.5 molecule having between 1 to 5 labile C.sub.1 -C.sub.5 acyl containing groups.

Brief Summary Text (25):

Alternatively, in order to prevent premature reaction of the hydrogen peroxide or its precursor with the source of acetyl groups, an anhydrous formulation containing both the source of acetyl groups and hydrogen peroxide or its precursor is provided. The hydrogen peroxide or its precursor, and the the source of acetyl groups, upon placement against the stained tooth surface in the oral cavity, are activated by the aqueous content of the saliva to generate a peroxyacid, such as peroxyacetic acid.

Brief Summary Text (26):

Alternatively, a composition may be manufactured having each of the hydrogen peroxide or its precursor and the source of acetyl groups as a separate and distinct component. According to this aspect of the invention, one component containing the source of acetyl groups may be applied to a stained tooth surface followed immediately thereafter by application onto the same tooth surface of a second component containing hydrogen peroxide or a hydrogen peroxide precursor. The sequence of application of such components may also be reversed depending upon the desired application. Such a sequential application would provide for the production of peroxyacetic acid *in situ* and is advantageously beneficial to accessing chromogens in tooth structures.

Brief Summary Text (27):

According to an additional aspect of the present invention, the first component containing a source of acetyl groups is applied to the tooth and is allowed for a sufficient time period to penetrate into pores present in the tooth structure. The second component containing the peroxide precursor is then applied which then advantageously provides for the generation of peroxyacid at locations deep within the tooth structure to thereby interact with chromogens that may also be within the tooth structure resulting in enhanced tooth whitening.

Brief Summary Text (29):

The peroxide precursor is present in the compositions of the present invention as they are applied directly to the tooth surface in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15

percent by weight. Higher levels of hydrogen peroxide may be used in conjunction with a supervised dental whitening procedure in which the soft tissue (i.e., the gingival and other mucosal surfaces) are physically isolated from the teeth being whitened. Hydrogen peroxide concentrations up to about 3 percent are acceptable for short-term (less than 60 minutes) incidental contact with soft tissue.

Brief Summary Text (30):

Compositions that utilize hydrogen peroxide itself, rather than a precursor, should be prepared as two or more components, keeping the source of acetyl groups in one component and hydrogen peroxide in the second component as an aqueous solution containing both hydrogen peroxide and the source of acetyl groups will quickly form a peroxyacid.

Brief Summary Text (34):

The use of glyceryl triacetate is advantageous due to its highly labile acetyl functionalities (which is important to obtaining effective tooth whitening levels of peroxyacetic acid in the presence of hydrogen peroxide), its low level of oral toxicity, and its unexpected ability to penetrate into intact tooth enamel upon contact to a tooth surface. Additionally, glyceryl triacetate degrades, in the presence of peroxide, into acetic acid (after first converting to peroxyacetic acid), water, and other degradation products that are toxicologically acceptable. While not wishing to be bound to any particular theory, the tightly packed crystal structure of tooth enamel and, to a lesser degree, dentin renders the tooth relatively impermeable to high molecular weight compounds such as proteins and polysaccharides. In addition, both the hydroxyapatite crystals and their supporting collagen matrix act as permselective barriers to diffusion of many types of molecules. In particular, highly polar or strongly charged ionic species (such as amines and glycols) do not penetrate the tooth structure to the same degree as relatively non-polar or uncharged species. The source of labile acetyl groups advantageously has a sufficiently low molecular weight which allows it to penetrate pores within teeth. Suitable compounds will have molecule weights below 1000, preferably below 500 and most preferably in a range similar to glyceryl triacetate, i.e. between 300 and 100.

Brief Summary Text (36):

According to an additional embodiment, the pH of the tooth whitening composition may be controlled during use as the generation of peroxyacid from hydrogen peroxide and glyceryl triacetate is pH-dependent.

Brief Summary Text (37):

The composition of the present invention may be applied to the stained tooth surface as liquids, gels, pastes, sprays, or as solid delivery systems (for instance, chewing gum or dental floss). The composition may be applied to the tooth surface in the form of a single component anhydrous formulation, a multi-component anhydrous or aqueous formulation mixed prior to application, or a multi-component anhydrous or aqueous formulation mixed directly on the tooth surface by sequential application of two or more components.

Brief Summary Text (38):

The peroxyacids of the present invention advantageously possess a high degree of antimicrobial activity. Accordingly, the compositions of the present invention are envisioned to have useful antimicrobial activity in addition to the desired tooth whitening effects. This activity may cause the destruction of oral microorganisms responsible for the formation of plaque (and eventually tartar), thus adding significantly to the potential utility of the present invention.

Brief Summary Text (40):

Carriers for inventive single component compositions should be toxicologically benign and include glycerin, propylene glycol, and polyethylene glycols. Such carriers may include chewing gum and gum base products, and floss carriers and floss wax products. An oil-based carrier is also useful, especially when combined with a surfactant capable of emulsifying the composition upon contact with water. Such oils include both vegetable and mineral oils, in addition to their higher molecular weight counterpart waxes and esters. Carriers for multi-component compositions include all of the above in addition to water. It is to be understood that

additional useful carriers will become apparent to those skilled in the art based upon the disclosure herein. The carrier portion of the inventive compositions, which may be composed of one or more individual components, and which may include such components as thickeners, buffering compounds, chelating agents, stabilizers, surfactants, sweeteners, and flavorants, is present at a level of from about 79 percent of the composition (in the form as it is applied to the tooth surface) to about 99.8 percent of the composition.

Brief Summary Text (41):

A thickener may also be added to increase contact time of either the single or multi-component composition on the tooth surface. This is particularly useful in tooth whitening methods where a dental tray is used to confine the material to a patient's dentition. Thickeners such as neutralized carboxypolyethylene and other polyacrylic acid polymers and copolymers, hydroxypropylcellulose and other cellulose ethers, salts of poly(methyl vinyl ether-co-maleic anhydride), poly(vinylpyrrolidone), poly(vinylpyrrolidone-co-vinyl acetate), silicon dioxide, fumed silica, stearic acid esters, and others are found to have utility in the formulation of tooth whitening compositions. The level of thickener, when present, is highly dependent upon the type chosen, but in general is included in the composition at a concentration of from about 0.5 percent by weight to about 20.0 percent by weight of the composition. It is to be understood that additional useful thickeners will become apparent to those skilled in the art based upon the disclosure herein.

Brief Summary Text (42):

The compositions of the present invention may also contain a buffer to provide a specific pH for optimal penetration of the composition into tooth enamel or to provide for optimal generation of peroxyacetic acid from the hydrogen peroxide precursor and glyceryl triacetate. Suitable buffers include sodium hydroxide, potassium hydroxide, ammonium hydroxide, sodium phosphate di- and tri-basic, potassium phosphate di- and tri-basic, sodium tripolyphosphate, tris(hydroxymethyl)aminomethane, triethanolamine, polyethylenimine, and other alkaline buffers. Within a particular formulation, an alkaline buffer may also serve the purpose of neutralizing carboxylic acid side chains in thickening polymers such as polyacrylic acid and poly(methyl vinyl ether-co-maleic anhydride). Acid buffers, such as citric acid, phosphoric acid, and others may also be used alone or in conjunction with an alkaline buffer to obtain the desirable pH and to provide buffering capacity. The level of buffer, when present, is from about 0.5 percent by weight to about 3.0 percent by weight of the composition. It is to be understood that additional useful buffers will become apparent to those skilled in the art based upon the disclosure herein.

Brief Summary Text (43):

The formation of peroxyacetic acid from hydrogen peroxide and glyceryl triacetate has been determined to occur most readily at pH levels in excess of about 5.2. However, peroxyacetic acid is only stable at an acid pH if formulated fully within a composition. Therefore, it is seen to be preferred to provide compositions that generate peroxyacetic acid *in situ* at a pH more suited to producing it quickly for use in the oral cavity. In this manner, tooth stains can be removed at a much more rapid rate through the use of the present compositions.

Brief Summary Text (46):

Surface active agents (surfactants) may be used to lower the surface tension of the compositions. Lowering of the surface tension allows for better wetting and spreading of the composition on the tooth surface. Some surfactants, such as zwitterionic and fluorinated surfactants, have been seen to increase the penetration of the present inventive compositions into the tooth structure. Useful surfactants include those identified in U.S. Pat. No. 5,279,816 and U.S. Pat. No. 5,302,375 each incorporated herein by reference in its entirety. It is to be understood that additional useful surfactants will become apparent to those skilled in the art based upon the disclosure herein. The level of surfactant, when present, is from about 0.1 to about 2.0 percent by weight of the composition.

Detailed Description Text (3):

In order to determine the ability of the inventive compositions to eliminate tooth

stain, a preliminary in vitro study on stained bovine enamel was performed.

Detailed Description Text (4):

Squares of dental enamel 4 mm on a side were cut, using a diamond-cutting disk, from bovine permanent incisors. Using a mold, the enamel squares were embedded in clear polyester casting resin (NATCOL Crafts Inc., Redlands, Calif.) to provide 1.5 cm square blocks with the labial surface exposed. The top surface of the polyester blocks was ground flush with the leveled labial surface of the enamel squares by means of a dental model trimmer. The surface was then smoothed by hand sanding on 400-grit emery paper using water as the lubricant until all grinding marks were removed. Finally, the top surface of the blocks was hand polished to a mirror finish using a water slurry of GK1072 calcined kaolin (median particle size=1.2 microns) on a cotton cloth. The finished specimens were examined under a dissecting microscope and were discarded if they had surface imperfections.

Detailed Description Text (5):

In preparation for the formation of artificial stained pellicle on the enamel, the specimens were etched for 60 seconds in 0.2M HCl followed by a 30-second immersion in a saturated solution of sodium carbonate. A final etch was performed with 1% phytic acid for 60 seconds, then the specimens were rinsed with deionized water and attached to the staining apparatus.

Detailed Description Text (6):

The pellicle staining apparatus was constructed to provide alternate immersion into the staining broth and air-drying of the specimens. The apparatus consisted of an aluminum platform base which supported a Teflon rod (3/4 inch in diameter) connected to an electric motor, which by means of a speed reduction box, rotated the rod at a constant rate of 1.5 rpm. Threaded screw holes were spaced at regular intervals along the length of the rod. The tooth specimens were attached to the rod by first gluing the head of a plastic screw to the back of a specimen. The screw is then tightened within a screw hole in the rod. Beneath the rod was a removable, 300-ml capacity trough, which held the pellicle, staining broth.

Detailed Description Text (10):

The difference between the pretreatment (baseline) and post-treatment readings for each color factor (L*, a*, and b*) represented the ability of a test solution to eliminate chromogens from the stained teeth.

Detailed Description Text (14):

It is clear from the comparative .DELTA.E values above that the stained enamel specimen labeled as sample "B" experienced a much more rapid whitening effect than sample "A", especially following the first few 30-minute treatments. It should be noted that sample B, after four treatments in Solution B containing 10% hydrogen peroxide and 6% glyceryl triacetate, experienced a large decrease in its b value (down to 5.84 from 10.68) during the 12 hour distilled water immersion between treatment days. Such an effect was not observed for sample A which was immersed in the 10% hydrogen peroxide solution alone.

Detailed Description Text (16):

A number of peroxyacid precursors were compared for their ability to whiten extracted teeth by the method described above. The following solutions were prepared by combining all of the ingredients in separate 4-oz borosilicate glass bottles with screw-on sealing caps.

Detailed Description Text (17):

Each of the above solutions was brushed onto the crown surface of an extracted human molar that had been previously graded for tooth shade. All of the teeth had an initial VITA shade of A3 and after treating each tooth with solution, its roots were wrapped with a moist paper towel in order to prevent any color change in the tooth due to dessication. Each tooth crown was then coated with the following gel composition.

Detailed Description Text (18):

After 60 minutes, each tooth was graded for color and the following results were recorded.

Detailed Description Text (24) :

A commercially available product used in an office setting by dentists utilizes 35% hydrogen peroxide and corresponds to a composition described in U.S. Pat. No. 5,032,178. A mixture to be applied to a stained tooth surface was prepared according to the manufacturer's instructions and used to determine its ability to remove tooth stain as above (a total of only two applications was done). The results are shown in Table 3 below.

Detailed Description Text (30) :

When water was mixed with the inventive composition (in a ratio of approximately 1 part water to 5 parts gel, by weight), the mixture quickly gave off an odor similar to acetic acid (vinegar-type smell), which was indicative of peroxyacetic acid generation. The composition was also placed on the surface of several extracted human teeth, whereby a visible whitening effect was seen after a 60 minute contact time.

Detailed Description Text (32) :

Another embodiment of the present invention, namely dual-component compositions, were prepared in a similar fashion to the manufacturing procedure outlined in Example IV, the only exception being that each component of the dual-component compositions in Table 5 below was prepared, packaged and stored separately, to be combined just prior to application to the tooth surface.

Detailed Description Text (33) :

After manufacture, each of the above compositions was placed in a separate chamber of a dual-chamber syringe, the type having a plunger mechanism whereby externally applied pressure to the plunger forces etch of the two components through a mixing chamber (known in the art as a static mixer) attached to the end of the dual-chambered syringe. A further description of this method of combining and mixing two incompatible components for the purpose of bleaching teeth can be found in the copending U.S. patent application Ser. No. 09/054,156 filed Apr. 2, 1998 hereby incorporated by reference in its entirety. Just prior to use, the two separate components are forced by the externally applied pressure into one end of the static mixer, travel through baffles in the static mixer which force the two components to blend together, and finally emerge from the opposite end of the static mixer as a single, homogeneous mixture. The resulting mixture thus contains both the hydrogen peroxide precursor and glyceryl triacetate, and alternatively, water in a sufficient amount to allow the production of peroxyacetic acid for whitening the teeth.

Detailed Description Text (34) :

In order to demonstrate the superior tooth whitening capabilities of the inventive compositions, tests on extracted human teeth were performed, whereby measurements of changes in qualitative color (VITA Shade Guide measurements, a method well known in the art) were taken.

Detailed Description Text (37) :

A further embodiment of the present invention provides for the combination of a hydrogen peroxide precursor and glyceryl triacetate *in situ*. In this mode of applying the inventive compositions, a first composition containing one of either the hydrogen peroxide element or the glyceryl triacetate element is placed directly onto the tooth surface to be whitened. A period of time may be allowed for the first element to penetrate into the tooth structure. Then, a second composition containing the remaining inventive composition element is placed directly onto the same tooth surface that has already been contacted with the first composition. In this manner, both the hydrogen peroxide precursor element and the glyceryl triacetate element are present on the stained tooth surface simultaneously. Peroxyacetic acid is thereby generated on and within the stained tooth providing a method of applying the inventive compositions (and whitening teeth in general) having certain advantages over other approaches.

Detailed Description Text (38) :

Since peroxyacids (and peroxides in general) are highly reactive species, an *in situ* method of applying and subsequently generating oxidizing agents on and within a stained tooth surface is advantageous. By generating the peroxyacid (in this

invention, peroxyacetic acid) on and within the tooth (thus in intimate contact with the stain-causing molecules themselves), superior tooth whitening results may be obtained. Although not wishing to be bound by any particular theory, it is believed that deeper penetration into the tooth structure by a first element (one of either a hydrogen peroxide precursor composition or a glyceryl triacetate composition) prior to contact with the second element will generate peroxyacetic acid (upon placement of the second remaining element) at the same site reached by the first element. In this manner, the depth at which tooth whitening occurs by the inventive compositions may be controlled. The *in situ* method described above has an additional advantage, in that the amount of peroxyacetic acid can be limited to that amount formed within the tooth structure itself (i.e. only where both of the required elements are present simultaneously). Accordingly, one aspect of the present invention involves the application of a composition or component of the composition onto the tooth surface and then allowing the composition or a first component of the composition to penetrate within the tooth structure itself. Peroxyacid is then allowed to generate within the tooth structure by application of an aqueous solution or a second component capable of reacting with the first component to generate a peroxyacid.

Detailed Description Text (39):

This *in situ* tooth whitening method may also be used with other peroxyacid precursors other than, and/or in addition to, glyceryl triacetate. Such peroxyacid precursors include all water-soluble or partially water-soluble compounds containing at least one acetyl group functionality, including, but not limited to acetylated amino acids (such as acetyl cysteine, acetyl glycine, etc) and acetylated polymers. Due to the desired penetration into the tooth structure in order to reach deeper stains, low molecular weight (<1000) acetyl group-containing molecules are preferred.

Detailed Description Text (44):

Chewing gum containing a thin slurry coating of sodium percarbonate and glyceryl triacetate in vegetable oil was prepared. A slurry of sodium percarbonate was first made by manually stirring approximately 2.0 percent by weight of sodium percarbonate powder (Solvay FB 100) into a mixture of 20 parts highly refined avocado oil (Super Refined Avocado Oil, Croda, Inc) and 1 part glyceryl triacetate (by volume). A portion of the resulting slurry (approximately 0.30 grams) was brushed onto the surface of a stick of a commercially available chewing gum (Extra, Wm. Wrigley & Son, Chicago, Ill.) and allowed to absorb overnight.

Detailed Description Text (45):

When manually kneaded in the presence of surface moisture provided by dabbing the gum bolus onto a wet surface, a slight odor of peroxyacetic acid was detected after about 30 seconds. It is expected that a similar result would be obtained upon chewing a stick of gum similarly prepared, thus providing peroxyacetic acid to the oral cavity, including the surface of the teeth.

Detailed Description Paragraph Table (8):

TABLE 5 Percent (w/w) A B B C Ingredient 1 2 1 2 1 2 Propylene glycol 42.56 45.00 Polyethylene glycol 400 70.00 73.40 Polyethylene glycol 600 23.00 33.90 Glycerin 5.00 5.00 5.00 Distilled water 2.67 69.24 82.80 Sodium saccharin 0.80 0.80 Potassium acesulfame 1.00 Dequest 2010 0.10 0.40 Sodium stannate 0.02 Flavor 0.80 1.00 1.20 Carbopol 974P 2.00 2.00 5.00 Hydroxypropylcellulose 10.00 10.00 Polyvinylpyrrolidone 10.00 10.00 Fumed silica 12.00 12.00 Poly(vinylpyrrolidone-co-vinyl acetate) 1.00 Sodium hydroxide monohydrate 2.67 Ammonium hydroxide 29% 3.20 3.20 Carbamide peroxide 12.00 Sodium percarbonate powder 8.00 Hydrogen peroxide 35% 17.14 Glyceryl triacetate 2.50 2.00 1.60 TOTAL 100.00 100.00 100.00 100.00 100.00 100.00

CLAIMS:

1. A method for whitening teeth comprising:

forming a composition having a pH in excess of about 5.2 by combining a hydrogen peroxide precursor in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the oral care composition, glyceryl triacetate in an amount between about 0.1

percent by weight to about 6.0 percent by weight of the oral care composition, and water so as to generate peroxyacetic acid; and
contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

2. A method for whitening teeth comprising:

providing separately glyceryl triacetate and a hydrogen peroxide releasing compound, both in an orally safe and sufficient amount for whitening teeth;

forming a composition having a pH in excess of about 5.2 including a mixture between the glyceryl triacetate and the hydrogen peroxide releasing compound with the glyceryl triacetate being in an amount between about 0.1 percent by weight to about 6.0 percent by weight of the composition and with the hydrogen peroxide releasing compound being in an amount sufficient to result in a hydrogen peroxide concentration of from about 0.1 percent by weight to about 15 percent by weight of the composition; and

contacting the composition to a surface of a tooth in an oral cavity for sixty minutes or less.

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L9: Entry 5 of 15

File: USPT

Feb 17, 1998

DOCUMENT-IDENTIFIER: US 5718886 A

TITLE: Stabilized anhydrous tooth whitening gel**Abstract Text (1):**

Stabilized anhydrous dental whitening gel compositions are provided which resist viscosity degradation during oral use. An illustrative anhydrous dental bleaching gel composition embodying this feature comprises propylene glycol, polyethylene glycol, glycerin in an amount not exceeding about 10 wt. %, neutralized carboxypolymethylene, hydroxypropylcellulose, xanthan gum and carbamide peroxide.

Parent Case Text (2):

This application is a continuation-in-part of U.S. patent application Ser. No. 08/599,364 filed Mar. 11, 1996 now U.S. Pat. No. 5,631,000 and entitled Anhydrous Tooth Whitening Gel.

Brief Summary Text (2):

This invention relates to dental compositions and, more particularly, to stabilized anhydrous tooth whitening gel compositions, a method for preparing the gel compositions, and a method for utilizing the gel compositions.

Brief Summary Text (4):

In that aspect of aesthetic dentistry which relates to self-administered use of in-home tooth whitening compositions, the dental patient is provided with a custom-fitted dental tray having selectively enlarged tooth treating compartments which are adapted to receive a whitening gel that is dispensed from a syringe. The dental tray, with its gel content, is unobtrusively and advantageously worn by the patient at night and while the patient sleeps. This treatment is repeated for a sufficient period of time to effect the tooth bleaching and whitening process.

Brief Summary Text (5):

It is disclosed in the prior art that carboxypolymethylene as well as methylcellulose can be used as the gelation agents in the formulation of tooth whitening gels. The prior art also discloses that carbamide peroxide (urea peroxide) as well as hydrogen peroxide can be used as the whitening agents in the formulation of tooth whitening gels.

Brief Summary Text (6):

U.S. Pat. No. 5,290,566 (Schow, et al., 1994) discloses a tooth whitening gel containing urea peroxide (carbamide peroxide), methylcellulose and water wherein the concentration of urea peroxide is from about 22 to about 32 wt. %.

Brief Summary Text (7):

U.S. Pat. Nos. 5,098,303 (Fischer, 1992), 5,234,342 (Fischer, 1993), 5,376,006 (Fischer, 1994) and 5,409,631 (Fischer, 1995), which are incorporated herein by reference, disclose tooth bleaching and whitening gel compositions formulated with carbamide peroxide, water, glycerin, carboxypolymethylene and sodium hydroxide. With respect to broad range ingredient concentration, the formulations contain from about 3.0 to about 20 wt. % carbamide peroxide, from about 10 to about 60 wt. % water, from about 20 to about 70 wt. % glycerin, from about 3.5 to about 12 wt. % carboxypolymethylene and sodium hydroxide in an amount to substantially neutralize the carboxypolymethylene. The gel is characterized as comprising a saturated or super saturated carboxypolymethylene composition wherein the actual concentration of carboxypolymethylene in the total quantity of water in the gel composition is in the

range from about 15% to about 40%, with the concentrated carboxypolymethylene providing the gel composition with a tackiness or stickiness. As to gel preparation, the patentee recommends that the carboxypolymethylene be mixed with glycerin and the resulting admixture dispersed in water, followed by the addition of the remaining ingredients, namely, sodium hydroxide and carbamide peroxide.

Brief Summary Text (8):

It has been observed that carbamide peroxide tooth whitening gels containing relatively high concentrations of water, glycerin and carboxypolymethylene (a) tend to have limited package stability as a result of the interaction of carbamide peroxide with water, (b) tend to increase tooth sensitivity as a result of the hygroscopic properties of glycerin which can reduce the moisture level at the tooth treatment surface, and (c) tend to string from one tooth treating compartment in the bleaching tray to the next tooth treating compartment in the tray in the course of syringe loading the compartments with the bleaching gel.

Brief Summary Text (9):

Although the foregoing limitations have been addressed by the development and use of anhydrous tooth whitening gels, it has now been observed that tooth whitening gels formulated with thickeners such as carboxypolymethylene and/or cellulotics exemplified by carboxymethylcellulose, hydroxymethylcellulose and hydroxypropylcellulose tend to decrease in viscosity with an increase in temperature. During overnight oral application of the tooth whitening gel, the temperature of the gel in the dental tray can increase from ambient to about 37.degree. C. (98.6.degree. F.). As a result of this rise in temperature, the gel tends to thin and become somewhat flowable. If the gel gets too thin, it may flow out of the tray and into contact with the soft tissue, causing tissue irritation.

Brief Summary Text (11):

An important object of the present invention is to provide new and improved dental whitening compositions which address the viscosity limitations of the prior art tooth whitening gels as hereinabove described.

Brief Summary Text (12):

Another object of this invention is to provide tooth whitening gel compositions which enable a reduced concentration of carboxypolymethylene to be used as a thickener without impairing the requisite viscosity characteristics of the gel compositions during oral use.

Brief Summary Text (13):

A further object of this invention is to provide tooth whitening gel compositions which resist viscosity degradation during oral use.

Brief Summary Text (14):

An additional object of this invention is to provide tooth whitening gel compositions which retain their viscosity in the presence of an increase in temperature and a decrease in pH that are encountered during oral use.

Brief Summary Text (16):

In accordance with one aspect of this invention, there is provided a tooth whitening composition containing carbamide peroxide dispersed in a substantially anhydrous gelatinous carrier. The anhydrous carrier comprises a polyol component wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition. The anhydrous carrier also comprises a thickener component containing neutralized carboxypolymethylene, cellulosic ether soluble in the polyol component and a viscosity stabilizer comprising xanthan gum.

Brief Summary Text (17):

In accordance with a second aspect of this invention, there is provided a method for whitening teeth which comprises (1) extruding a substantially anhydrous tooth whitening gel composition into the reservoir system of a dental bleaching tray, (2) placing the dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened, (3) maintaining the gel composition in contact with the aforesaid teeth for a plurality of hours per day, and (4) repeating steps 1, 2 and 3 for multiple days to effect whitening of the teeth. The anhydrous

tooth whitening gel composition which can be used in carrying out the method advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 50 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 55 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %, (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %.

Brief Summary Text (18):

In accordance with a third aspect of this invention, there is provided a method for preparing substantially anhydrous dental whitening gel compositions. The method comprises admixing a settable ingredient mix to obtain a homogenous dispersion of the ingredients. The settable ingredient mix advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %, (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %, (i) wherein weight percent is based on the total weight of the gel composition.

Brief Summary Text (20):

The dental whitening gel compositions of this invention comprise carbamide peroxide dispersed in an anhydrous gelatinous carrier. Carbamide peroxide is generally present in the anhydrous gel compositions in an amount from about 5 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Brief Summary Text (22):

Glycerin can also be used as a constituent of the liquid component. However, glycerin is hygroscopic and a high concentration of glycerine in the gel tends to pull moisture away from the surface of the teeth which can lead to increased dental sensitivity to the bleaching composition. Accordingly, if glycerin is used in the bleaching gel, it should be limited to a concentration that does not exceed about 10 wt. % of the gel composition. In a more specific aspect, glycerin can be present in the gel composition in an amount from about 3.0 wt. % to about 9.0 wt. %.

Brief Summary Text (24):

Cellulosic ether is generally present in the gel compositions in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. %. A preferred cellulosic ether is hydroxypropylcellulose.

Brief Summary Text (25):

The blend of neutralized carboxypolymethylene and cellulosic ether is particularly advantageous because the blend provides the gel compositions with improved thixotropic properties in respect of flow-set characteristics. This rheological enhancement constitutes an improvement in the dental whitening art because it tends to minimize the stringing and roping of the gel from one tooth treating compartment to the next tooth treating compartment during the sequential syringe loading of the gel into the compartments of the dental whitening tray.

Brief Summary Text (27):

The anhydrous tooth whitening gels of this invention are prepared by adding and mixing the ingredients of the formulation in a suitable vessel such as a stainless steel tank that is provided with a heavy duty mixer which is suitable for use with thick gels. If desired, the mixing vessel can be combined with vacuum equipment for carrying out the admixing of the ingredients under vacuum conditions. The ingredients of the formulation are mixed to obtain a homogenous dispersion which sets to a thixotropic gel.

Brief Summary Text (28):

In the preparation of the dental whitening gels, the formulating ingredients are advantageously added to the mixing vessel in the following order: liquid ingredients, thickener ingredients, alkalinizing agent, carbamide peroxide, and any desired flavoring.

Brief Summary Text (29):

The quantities of the formulating ingredients are so selected as to provide the whitening gels with a composition containing (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. % and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. % and, preferably, in an amount from about 3.0 wt. % to about 9.0 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. % and, preferably, in an amount from about 1.5 wt. % to about 2.5 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. % (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. % and, preferably, in an amount from about 0.3 wt. % to about 1.3 wt. %, (g) neutralizing reagent, preferably, anhydrous sodium hydroxide in an amount to substantially neutralize carboxypolymethylene, and (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Detailed Description Text (2):

The following examples further illustrate the anhydrous tooth whitening gels of this invention and the concentration ranges for the ingredients thereof. As used in the examples, "PEG" is a trade designation for polyethylene glycol (Merck Index No. 7545, 11th ed.), "Carbopol" is a trademark for carboxypolymethylene (Merck Index No. 1836, 11th ed.) and "Klucel" is a trademark for hydroxypropylcellulose (Merck Index No. 4776, 11th ed.). The bleaching gels were prepared in accordance with the method and procedure as hereinabove described.

Detailed Description Text (3):

The anhydrous tooth whitening gel compositions, as hereinabove described, are packaged in appropriate syringes for dispensing into custom-fitted dental trays that are usually worn at night, but can also be worn during the day, with maximum whitening generally occurring when the treatment is continued for ten to fourteen days. The custom-fitted dental bleaching trays can be prepared by using materials and procedures that are well known in the dental art, and which are described in the prior art cited herein.

Detailed Description Text (4):

In a first alternative packaging embodiment, the dental whitening gels can be packaged in gel dispensing tubes or bottles for extrusion into general purpose dental trays for carrying out the dental whitening process. In a second alternative packaging embodiment, pre-packaged dental trays can be provided to the user containing dental whitening gels which have been adapted for this purpose.

Detailed Description Paragraph Table (1):

| | | Weight Percent Ingredients | Ex. 1 | Ex. 2 | Ex. 3 |
|------------------|-------|----------------------------|------------|-------|------------------|
| Ex. 4 | Ex. 5 | Propylene glycol | 47.4 | 49.0 | 45.4 |
| 43.4 | 48.4 | PEG 600 | 20.0 | 21.7 | -- |
| | | PEG 1000 | 10.0 | 11.7 | -- |
| | | PEG 1450 | -- | -- | 15.0 |
| -- | 26.0 | 6.0 | -- | -- | PEG 1500 |
| -- | 26.0 | PEG 1500 | -- | -- | -- |
| | | Glycerin | 8.0 | 8.0 | 8.0 |
| | | Carbopol 980 | 2.2 | 2.2 | 2.2 |
| 2.2 | 2.2 | 2.2 | Klucel GFF | 1.7 | 1.5 |
| 2.2 | 2.2 | 2.2 | 1.0 | 0.8 | 1.3 |
| Flavor | 0.2 | 0.2 | 0.2 | 0.2 | Sodium hydroxide |
| 0.2 | 0.2 | 0.2 | 0.2 | 0.2 | 0.4 |
| 10.0 | 5.0 | 16.0 | 22.0 | 10.0 | 100.0 |
| | | | | 100.0 | 100.0 |
| | | | | | 100.0 |
| | | Weight Percent Ingredients | Ex. 6 | Ex. 7 | Ex. 8 |
| Ex. 9 | | Propylene glycol | 46.4 | 45.4 | 54.2 |
| PEG 600 | -- | PEG 1000 | 31.0 | 16.0 | -- |
| -- | 28.0 | PEG 1450 | -- | 16.0 | -- |
| -- | 28.0 | PEG 1500 | -- | -- | -- |
| -- | 35.2 | Glycerin | 8.0 | 8.0 | 0.2 |
| -- | 35.2 | Carbopol 980 | 2.1 | 2.0 | 0.5 |
| 1.5 | 1.0 | Xanthan gum | 0.1 | 0.2 | 2.0 |
| 1.5 | 1.0 | Klucel MFF | -- | 0.8 | -- |
| 1.5 | 1.0 | Flavor | 0.2 | 0.2 | 0.2 |
| Sodium hydroxide | 0.4 | 0.4 | 0.4 | 0.4 | 0.4 |
| 100.0 | 100.0 | Carbamide peroxide | 10.0 | 10.0 | 16.0 |
| 100.0 | 100.0 | | 100.0 | 100.0 | 100.0 |

CLAIMS:

1. A tooth whitening gel composition comprising carbamide peroxide dispersed in an anhydrous gelatinous carrier, said carrier comprising:
 - (a) a polyol component wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition;
 - (b) a thickener component containing neutralized carboxypolymethylene and cellulosic either soluble in the polyol component; and
 - (c) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. % for stabilizing the gel composition against viscosity degradation during oral use.
6. The composition of claim 1 wherein the concentration of carbamide peroxide is from about 5.0 wt. % to about 25 wt. %.
7. An anhydrous tooth whitening gel composition comprising:
 - (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
 - (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
 - (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
 - (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
 - (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
 - (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %,
 - (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
 - (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %.
11. The composition of claim 7 wherein carboxypolymethylene is present in an amount from about 1.5 wt. % to about 2.5 wt. % and hydroxypropylcellulose is present in an amount from about 1.0 wt. % to about 3.0 wt. %.
12. The composition of claim 7 wherein carbamide peroxide is present in an amount from about 10 wt. % to about 20 wt. %.
13. A method for whitening teeth which comprises:
 - (1) extruding an anhydrous teeth whitening gel composition into the reservoir system of a teeth bleaching dental tray, said gel composition comprising:
 - (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
 - (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
 - (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
 - (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
 - (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
 - (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %,
 - (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and

- (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %;
- (2) placing said dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened;
- (3) maintaining said gel composition in contact with said teeth for a plurality of hours per day; and
- (4) repeating steps 1, 2 and 3 for multiple days to thereby whiten the teeth.

15. The method of claim 13 wherein glycerin is present in the gel composition in an amount from about 3.0 wt. % to about 9.0 wt. %; carboxypolymethylene is present in the gel composition in an amount from about 1.5 wt. % to about 2.5 wt. %; and hydroxypropylcellulose is present in the gel composition in an amount from about 1.0 wt. % to about 3.0 wt. %.

16. A method for preparing an anhydrous tooth whitening gel composition, which method comprises admixing:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) xanthan gum in an amount from about 0.1 wt. % to about 1.5 wt. %,
- (g) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (h) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %,
- (i) wherein weight percent is based on the total weight of the gel composition.

17. The method of claim 16 wherein the amount of glycerin is from about 3.0 wt. % to about 9.0 wt. %, the amount of carboxypolymethylene is from about 1.5 wt. % to about 2.5 wt. %, the amount of hydroxypropylcellulose is from about 1.0 wt. % to about 3.0 wt. %, and the amount of xanthan gum is from about 0.3 wt. % to about 1.3 wt. %.

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L9: Entry 7 of 15

File: USPT

May 20, 1997

DOCUMENT-IDENTIFIER: US 5631000 A
TITLE: Anhydrous tooth whitening gel

Abstract Text (1):

An anhydrous dental bleaching gel composition is provided which has improved package stability, improved rheology and reduced sensitivity during use. An illustrative anhydrous dental bleaching gel composition embodying these features comprises propylene glycol, polyethylene glycol, glycerin in an amount not exceeding about 10 wt. %, neutralized carboxypolymethylene, hydroxypropylcellulose, and carbamide peroxide.

Brief Summary Text (2):

This invention relates to dental compositions and, more particularly, to anhydrous tooth whitening gel compositions, a method for preparing the gel compositions, and a method for utilizing the gel compositions.

Brief Summary Text (4):

In that aspect of aesthetic dentistry which relates to self-administered use of in-home tooth whitening compositions, the dental patient is provided with a custom-fitted dental tray having selectively enlarged tooth treating compartments which are adapted to receive a whitening gel that is dispensed from a syringe. The dental tray, with its gel content, is unobtrusively and advantageously worn by the patient at night and while the patient sleeps. This treatment is repeated for a sufficient period of time to effect the tooth bleaching and whitening process.

Brief Summary Text (5):

It is disclosed in the prior art that carboxypolymethylene as well as methylcellulose can be used as the gelation agents in the formulation of tooth whitening gels. The prior art also discloses that carbamide peroxide (urea peroxide) as well as hydrogen peroxide can be used as the whitening agents in the formulation of tooth whitening gels.

Brief Summary Text (6):

U.S. Pat. No. 5,290,566 (Schow, et al., 1994) discloses a tooth whitening gel containing urea peroxide (carbamide peroxide), methylcellulose and water wherein the concentration of urea peroxide is from about 22 to about 32 wt. %.

Brief Summary Text (7):

U.S. Pat. No. 5,098,303 (Fischer, 1992), U.S. Pat. No. 5,234,342 (Fischer, 1993), U.S. Pat. No. 5,376,006 (Fischer, 1994) and U.S. Pat. No. 5,409,631 (Fischer, 1995), which are incorporated herein by reference, disclose tooth bleaching and whitening gel compositions formulated with carbamide peroxide, water, glycerin, carboxypolymethylene and sodium hydroxide. With respect to broad range ingredient concentration, the formulations contain from about 3.0 to about 20 wt. % carbamide peroxide, from about 10 to about 60 wt. % water, from about 20 to about 70 wt. % glycerin, from about 3.5 to about 12 wt. % carboxypolymethylene and sodium hydroxide in an amount to substantially neutralize the carboxypolymethylene. The gel is characterized as comprising a saturated or super saturated carboxypolymethylene composition wherein the actual concentration of carboxypolymethylene in the total quantity of water in the gel composition is in the range from about 15% to about 40%, with the concentrated carboxypolymethylene providing the gel composition with a tackiness or stickiness. As to gel preparation, the patentee recommends that the carboxypolymethylene be mixed with glycerin and the resulting admixture dispersed in

water, followed by the addition of the remaining ingredients, namely, sodium hydroxide and carbamide peroxide.

Brief Summary Text (8):

It has been observed that carbamide peroxide tooth whitening gels containing relatively high concentrations of water, glycerin and carboxypolymethylene (a) tend to have limited package stability as a result of the interaction of carbamide peroxide with water, (b) tend to increase tooth sensitivity as a result of the hygroscopic properties of glycerin which can reduce the moisture level at the tooth treatment surface, and (c) tend to string from one tooth treating compartment in the bleaching tray to the next tooth treating compartment in the tray in the course of syringe loading the compartments with the bleaching gel.

Brief Summary Text (10):

An important object of the present invention is to provide new and improved dental whitening compositions which address the limitations of the prior art dental bleaching gels as hereinabove described.

Brief Summary Text (11):

Another object of this invention is to provide dental whitening compositions which have improved package stability with respect to the active bleaching agent, namely, the peroxide constituent.

Brief Summary Text (12):

A further object of this invention is to provide dental whitening compositions which have reduced sensitivity during use.

Brief Summary Text (13):

An additional object of this invention is to provide dental whitening compositions which have improved thixotropic properties with respect to flow-set characteristics.

Brief Summary Text (15):

In accordance with one aspect of this invention, there is provided a dental whitening composition containing carbamide peroxide dispersed in a substantially anhydrous gelatinous carrier. The anhydrous carrier comprises a liquid component wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition. The anhydrous carrier also comprises a thickener component containing neutralized carboxypolymethylene and cellulosic ether soluble in the liquid component.

Brief Summary Text (16):

In accordance with a second aspect of this invention, there is provided a method for whitening teeth which comprises (1) extruding a substantially anhydrous dental bleaching gel composition into the reservoir system of a dental bleaching tray, (2) placing the dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened, (3) maintaining the gel composition in contact with the aforesaid teeth for a plurality of hours per day, and (4) repeating steps 1, 2 and 3 for multiple days to effect whitening of the teeth. The anhydrous dental bleaching gel composition which can be used in carrying out the method advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 50 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 55 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %.

Brief Summary Text (17):

In accordance with a third aspect of this invention, there is provided a method for preparing substantially anhydrous dental whitening gel compositions. The method comprises admixing a settable ingredient mix to obtain a homogenous dispersion of the ingredients. The settable ingredient mix advantageously comprises (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %, (b) polyethylene glycol

in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. % (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %, (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %, (h) wherein weight percent is based on the total weight of the gel composition.

Brief Summary Text (19):

The dental whitening gel compositions of this invention comprise carbamide peroxide dispersed in an anhydrous gelatinous carrier. Carbamide peroxide is generally present in the anhydrous gel compositions in an amount from about 5 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Brief Summary Text (21):

Glycerin can also be used as a constituent of the liquid component. However, glycerin is hygroscopic and a high concentration of glycerine in the gel tends to pull moisture away from the surface of the teeth which can lead to increased dental sensitivity to the bleaching composition. Accordingly, if glycerin is used in the bleaching gel, it should be limited to a concentration that does not exceed about 10 wt. % of the gel composition. In a more specific aspect, glycerin can be present in the gel composition in an amount from about 3.0 wt. % to about 9.0 wt. %.

Brief Summary Text (23):

Cellulosic ether is generally present in the gel compositions in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. %. A preferred cellulosic ether is hydroxypropylcellulose.

Brief Summary Text (24):

The blend of neutralized carboxypolymethylene and cellulosic ether is particularly advantageous because the blend provides the gel compositions with improved thixotropic properties in respect of flow-set characteristics. This rheological enhancement constitutes an improvement in the dental bleaching art because it tends to minimize the stringing and roping of the gel from one tooth treating compartment to the next tooth treating compartment during the sequential syringe loading of the gel into the compartments of the dental bleaching tray.

Brief Summary Text (25):

The anhydrous dental bleaching gels of this invention are prepared by adding and mixing the ingredients of the formulation in a suitable vessel such as a stainless steel tank that is provided with a heavy duty mixer which is suitable for use with thick gels. If desired, the mixing vessel can be combined with vacuum equipment for carrying out the admixing of the ingredients under vacuum conditions. The ingredients of the formulation are mixed to obtain a homogenous dispersion which sets to a thixotropic gel.

Brief Summary Text (26):

In the preparation of the dental whitening gels, the formulating ingredients are advantageously added to the mixing vessel in the following order: liquid ingredients, thickener ingredients, alkalinizing agent, carbamide peroxide, and any desired flavoring.

Brief Summary Text (27):

The quantities of the formulating ingredients are so selective as to provide the whitening gels with a composition containing (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. %, (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. % and, preferably, in an amount from about 25 wt. % to about 45 wt. % and having a molecular weight from about 400 to about 1500, (c) glycerin in an amount from about 0 wt. % to about 10 wt. % and, preferably, in an amount from about 3.0 wt. % to about 9.0 wt. %, (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. % and, preferably, in an amount from about 1.5 wt. % to about 2.5 wt. %, (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. % and, preferably, in an amount from about 1.0 wt. % to about 3.0 wt. %, (f)

neutralizing reagent, preferably, anhydrous sodium hydroxide in an amount to substantially neutralize carboxypolyethylene, and (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. % and, preferably, in an amount from about 10 wt. % to about 20 wt. %.

Detailed Description Text (2):

The following examples further illustrate the anhydrous dental bleaching gels of this invention and the concentration ranges for the ingredients thereof. As used in the examples, "PEG" is a trade designation for polyethylene glycol (Merck Index No. 7545, 11th ed.), "Carbopol" is a trademark for carboxypolymethylene (Merck Index No. 1836, 11th ed.) and "Klucel" is a trademark for hydroxypropylcellulose (Merck Index No. 4776, 11th ed.). The bleaching gels were prepared in accordance with the method and procedure as hereinabove described.

Detailed Description Text (3):

The anhydrous dental whitening gel compositions, as hereinabove described, are packaged in appropriate syringes for dispensing into custom-fitted dental trays that are usually worn at night, but can also be worn during the day, with maximum whitening generally occurring when the treatment is continued for ten to fourteen days. The custom-fitted dental bleaching trays can be prepared by using materials and procedures that are well known in the dental art, and which are described in the prior art cited herein.

Detailed Description Text (4):

In a first alternative packaging embodiment, the dental whitening gels can be packaged in gel dispensing tubes or bottles for extrusion into general purpose dental trays for carrying out the dental whitening process. In a second alternative packaging embodiment, pre-packaged dental trays can be provided to the user containing dental whitening gels which have been adapted for this purpose.

Detailed Description Paragraph Table (1):

Detailed Description Paragraph Table (2):

| | Weight Percent Ingredients | | | | | | | | | | Ex. 6 | Ex. 7 | Ex. 8 | | | | | | |
|-----------|----------------------------|------|------|----------|----------|-------|--------|-------|----------|----------|------------------|--------|-----------|------|----------|-----|-----|-----|-----|
| Ex. 9 | | | | | | | | | | | Propylene glycol | 46.4 | 45.4 | 54.2 | 41.1 | | | | |
| PEG 600 | -- | -- | 28.0 | -- | PEG 1000 | 31.0 | 16.0 | -- | -- | PEG 1450 | -- | 16.0 | -- | -- | PEG 1500 | -- | -- | | |
| -- | -- | -- | 35.2 | Glycerin | 8.0 | 8.0 | 3.0 | 3.0 | Carbopol | 980 | 2.2 | 2.2 | 2.0 | 3.0 | Klucel | GFF | 1.8 | 1.8 | 0.4 |
| 1.0 | Klucel | MFF | -- | -- | 0.8 | -- | Flavor | 0.2 | 0.2 | 0.2 | 0.2 | Sodium | hydroxide | 0.4 | 0.4 | 0.4 | 0.5 | | |
| Carbamide | peroxide | 10.0 | 10.0 | 11.0 | 16.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | 100.0 | | | | | | | | |

CLAIMS :

1. An anhydrous tooth whitening gel composition comprising carbamide peroxide dispersed in an anhydrous gelatinous carrier, said carrier comprising:

(a) a liquid polyol wherein glycerin, if present, is limited to an amount that does not exceed about 10 wt. % based on the total weight of the composition; and

(b) a thickener component containing neutralized carboxypolymethylene and cellulosic ether soluble in the liquid component,

said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

5. The composition of claim 1 wherein the concentration of carbamide peroxide is from about 5.0 wt. % to about 25 wt. %.

6. An anhydrous tooth whitening gel composition comprising:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %,

said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

11. The composition of claim 6 wherein hydroxypropylcellulose is present in an amount from about 1.0 wt. % to about 3.0 wt. %.

12. The composition of claim 6 wherein carbamide peroxide is present in an amount from about 10 wt. % to about 20 wt. %.

13. A method for whitening teeth which comprises:

(1) extruding an anhydrous tooth whitening gel composition into the reservoir system of a tooth bleaching dental tray, said gel composition comprising:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %, and having a molecular weight from about 400 to about 1500,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %;

(2) placing said dental tray in the oral cavity so as to bring the gel composition into contact with the teeth to be whitened;

(3) maintaining said gel composition in contact with said teeth for a plurality of hours per day; and

(4) repeating steps 1, 2 and 3 for multiple days to thereby whiten the teeth,
said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

16. The method of claim 13 wherein hydroxypropylcellulose is present in the gel composition in an amount from about 1.0 wt. % to about 3.0 wt. %.

17. A method for preparing an anhydrous tooth whitening gel composition, which method comprises admixing:

- (a) propylene glycol in an amount from about 10 wt. % to about 55 wt. %,
- (b) polyethylene glycol in an amount from about 10 wt. % to about 50 wt. %,
- (c) glycerin in an amount from about 0 wt. % to about 10 wt. %,
- (d) carboxypolymethylene in an amount from about 0.5 wt. % to about 3.0 wt. %,
- (e) hydroxypropylcellulose in an amount from about 0.5 wt. % to about 10 wt. %,
- (f) neutralizing reagent in an amount to substantially neutralize carboxypolymethylene, and
- (g) carbamide peroxide in an amount from about 5.0 wt. % to about 25 wt. %,
- (h) wherein weight percent is based on the total weight of the gel composition, said anhydrous tooth whitening gel composition having enhanced package stability, reduced tooth sensitivity, and improved thixotropic properties.

19. The method of claim 17 wherein the amount of carboxypolymethylene is from about 1.5 wt. % to about 2.5 wt. % and the amount of hydroxypropylcellulose is from about 1.0 wt. % to about 3.0 wt. %.

WEST Generate Collection

L9: Entry 10 of 15

File: USPT

Mar 28, 1995

DOCUMENT-IDENTIFIER: US 5401495 A

TITLE: Teeth whitenerAbstract Text (1):

A three component system and method for whitening teeth comprising a pre-conditioning mouth rinse, a bleaching gel, and a polishing and pigmenting paste wherein each component is applied to the teeth independently and in sequential order.

Brief Summary Text (1):

This invention relates in general to teeth whitening dentrifrices and more particularly to a new system containing a plurality of substances used in combination that is useful for whitening and polishing human teeth.

Brief Summary Text (2):

For a variety of reasons it has become desirable for a person's teeth to appear bright or "white." Society places a high value on the "whiteness" of one's teeth. One whose teeth are white may enjoy more personal confidence and satisfaction and may even enjoy greater social acceptance. In many business situations, such as acting and television newsreporting, a person's appearance is of the utmost importance in securing employment and having "white" teeth is known to be an asset.

Brief Summary Text (3):

A tooth is comprised of an inner dentin layer and an outer hard enamel layer that is the protective layer of the tooth. The enamel layer of a tooth is naturally an opaque white or slightly off-white color. It is this enamel layer that can become stained or discolored. The enamel layer of a tooth is composed of hydroxyapatite mineral crystals that create a somewhat porous surface. These hydroxyapatite crystals form microscopic hexagonal rods or prisms that make up the enamel surface. As a result, the surface of the enamel layer presents microscopic spaces or pores between the prisms. It is believed that this porous nature of the enamel layer is what allows staining agents and discoloring substances to permeate the enamel and discolor the tooth. These remaining substances can occupy the microscopic spaces and eventually alter the color of the tooth.

Brief Summary Text (4):

Many substances that a person confronts or comes in contact with on a daily basis can "stain" or reduce the "whiteness" of one's teeth. In particular, the foods, tobacco products and fluids that one consumes tend to stain one's teeth. These products or substances tend to accumulate on the enamel layer of the tooth and for a pellicle film over the teeth. These staining and discoloring substances can then permeate the enamel layer. This problem occurs gradually over many years, but imparts a noticeable discoloration of the enamel of one's teeth. So long as the discolored teeth are still healthy and do not pose any health risk or problem, a product or substance that would whiten the discolored teeth would be advantageous.

Brief Summary Text (5):

It is also essential that a teeth whitening product that is to be used at home or in private by the consumer be safe and easy to use. A product for home use cannot utilize some of the compositions or products for whitening teeth that are available for use by a trained dental professional. For example, a 35% hydrogen peroxide bleaching agent is utilized by many dental practitioners to bleach severely discolored teeth. Such a concentrated solution of hydrogen peroxide would be

irritating and potentially dangerous for home use by the consumer. Products and substances that are presently available to whiten teeth include a variety of different ingredients, but the primary active ingredient is an abrasive agent formulated into a gel or paste. These abrasive gel type products "polish" the enamel layer of the teeth to which it is applied and give it a more lustrous sheen and partially scrub away materials that stain the tooth enamel. These abrasive products are not able to perform all of the desired functions in a fully satisfactory manner.

Brief Summary Text (6):

It is therefore a primary object of the present invention to provide a system for whitening teeth that is more effective in whitening teeth and safer to use than existing products available to the consumer.

Brief Summary Text (7):

It is another object of the present invention to provide a system for whitening teeth that includes a cleansing mouth rinse, a bleaching substance and a pigmenting agent as well as an abrading and polishing agent to more completely and more efficiently whiten teeth than known products.

Brief Summary Text (8):

It is still another object of the present invention to provide a complete system for whitening the enamel of human teeth that is safe for home use and a method of use that can easily be performed by the consumer without the assistance of a trained dental professional.

Brief Summary Text (9):

It is a further object of the present invention to provide a system and method for whitening human teeth where the component parts of the system are to be used in a sequential manner to cosmetically whiten a person's teeth.

Brief Summary Text (10):

It is still a further object of the present invention to provide a teeth whitening product that includes an effective quantity of a bleaching agent such as hydrogen peroxide in a concentration that can be safely and comfortably used at home by the consumer.

Brief Summary Text (11):

It is yet a further object of the present invention to provide a product for whitening teeth that includes an effective quantity of hydrogen peroxide to bleach teeth in a manageable and convenient gel medium that can be applied with the use of an appropriate applicator.

Brief Summary Text (12):

It is an aim of the present invention to provide a product for whitening teeth that includes a pigmenting substance that is of a small enough particle size to fit into the pores or spaces between the hydryxyapatte crystals or enamel prisms that make up the enamel layer.

Brief Summary Text (13):

It is another aim of the present invention to provide a teeth whitening product that utilizes a pigmenting substance that imparts a white pigment to the enamel layer of the tooth and that also functions as an abrasive substance to polish the teeth.

Brief Summary Text (14):

It is a further aim of the present invention to provide a system for whitening teeth that can be safely and effectively be used on a daily basis to prevent further discoloration of the user's teeth.

Brief Summary Text (16):

The present invention is directed to an improved system and method for whitening teeth that has three separately formulated components having four primary active ingredients to serve as a complete and effective teeth whitener. The system includes a conditioning mouth rinse, a bleaching gel, and a polishing and pigmenting composition, wherein each component is applied independently and sequentially. In

accordance with the invention, the first component is a teeth cleansing mouth rinse formulated by preparing a dilute, aqueous solution of acetic acid in combination with flavor enhancers, a preservative, a surfactant and mixtures thereof. The second component of the system is a gel capable of bleaching teeth enamel and is formulated as a combination of hydrogen peroxide, a gelling agent capable of maintaining the stability of the hydrogen peroxide over a period of time, a neutralizing agent, a thickening agent and mixtures thereof. The third component of the teeth whitening system and method is a polishing cream or paste that includes a pigmenting agent. The polishing cream is formulated by combining deionized water, a carrier, an abrasive polishing agent, flavor enhancers, thickening agents, surfactants, a pigmenting agent and mixtures thereof. Alumina silicates are most useful as the abrasive and polishing agent and most preferred are synthetic precipitated amorphous alumina silicates sold under the trademarks ZEO-49 or ZEODENT 113 by the J. M. Huber Corp. of Harve de Grace, Md. The preferred carrier is glycerin and the most preferred pigmenting agent is titanium dioxide.

Brief Summary Text (18):

The components of the present teeth whitening system are to be used in a sequential fashion. The user first rinses his mouth and concomitantly his teeth with the conditioning mouth rinse of the invention. This is followed by applying the bleaching gel onto the teeth. This second component is applied onto the teeth for approximately 1-4 minutes and then the teeth are rinsed with water. Finally, the polishing and pigmented cream is brushed onto the teeth. This component of the system is brushed onto the teeth for about 1-3 minutes and left on the teeth as long as possible, preferably overnight.

Brief Summary Text (20):

In accordance with the invention, a three component teeth whitening system is provided. Each component is formulated and packaged separately. In formulating the components, pharmaceutical grade reagents, if available, should be used throughout and all necessary safety and sterility procedures should be employed for a product that will be used in contact with human teeth and oral tissues.

Brief Summary Text (21):

The first component of the teeth whitening system is a conditioning mouth rinse. This mouth rinse is comprised generally of an aqueous dilution of acetic acid. The preferred concentration range of the acetic acid in the solution is between 1%-3% and is most preferably between 0.5%-1.5% acetic acid. Normal white distilled or household vinegar can be used to prepare the mouth rinse.

Brief Summary Text (25):

In preparing the conditioning mouth rinse, deionized water is first heated to about 80.degree. C. and any preservative or sweetener is dissolved therein. The solution is then allowed to cool and an appropriate amount of 5% acetic acid is added to obtain the desired final concentration. At this point, a surfactant is added and any flavoring chemical or composition is likewise added. The resulting solution is stirred until all of the substances are fully dissolved. The rinse is now ready for its use in cleansing and debriding the pellicle film that accumulates on the enamel of teeth. The application of this rinse to a person's teeth pre-conditions the enamel layer of the teeth to be more accessible to the actions of the subsequent components of the whitening system.

Brief Summary Text (26):

The second component of the teeth whitening system of the present invention is a bleaching gel. The active ingredient in this bleaching component is hydrogen peroxide. This component of the whitening system uses a relatively low concentration of hydrogen peroxide in a gel form. A high concentration of hydrogen peroxide could not be used safely by the typical consumer and therefore the useful range of hydrogen peroxide in the gel is between 1%-10% hydrogen (by weight). The most preferred range is between 3%-6.5% and the most preferred concentration is 6% in the gel. Hydrogen peroxide generally has a pH of between 3-6 and is preferably maintained around 6. The hydrogen peroxide is prepared as a gel to provide a safe and easy form in which it may be applied onto the user's teeth. A liquid hydrogen peroxide formulation would be irritating to the gums and gingival tissues and would therefore not be as useful as the preferred easy to use gel form in accordance with the instant

invention.

Brief Summary Text (29):

The most preferred gelling agent is a water dispersible copolymer of acrylic acid cross-linked with approximately 0.75% to approximately 1.5% polyallyl sucrose that is sold under the trademark CARBOPOL 934 by B. F. Goodrich. This gelling agent is neutralized with triethanolamine or another suitable alkalinizing agent as discussed in U.S. Pat. No. 3,499,844 to achieve a pH of the final product around 3.5. In order to obtain the most useful gel for use in the present invention a sufficient amount of non-ionic cellulose or gum is added to the gel to improve the physical stability of the gel. This is basically a thickening agent and hydroxyethylcellulose gum, hydroxypropylcellulose gum or carboxymethyl cellulose work effectively and are preferred, although other like products would have utility.

Brief Summary Text (30):

In preparation, the bleaching gel that is the second component of the teeth whitening system preferably comprises 6% by weight of hydrogen peroxide, 2% of CARBOPOL 934 (an acrylic acid copolymer cross-linked with polyallyl sucrose), 1% of triethanolamine, 1% by weight of hydroxyethylcellulose, and the remainder is deionized water. This formulation is prepared by first combining an appropriate amount of a 35% aqueous solution of hydrogen peroxide with deionized water. This mixture is slowly stirred and CARBOPOL 934 is gradually added. After the gelling agent has become thoroughly dispersed in the hydrogen peroxide solution, the hydroxyethylcellulose is slowly added until it dissolves. Finally, 99% triethanolamine is diluted in a 1:1 ratio with deionized water and slowly added to the gelled solution to achieve a final pH of approximately 3.5. The resulting compound is clear, homogeneous, stable and viscous gel.

Brief Summary Text (31):

The bleaching gel can then be placed on an applicator such as a cotton swab and applied onto the teeth for 1-4 minutes. Alternatively, the bleaching gel may be applied directly to the teeth and allowed to remain in contact therewith for a like amount of time. The gel is then removed by rinsing with water.

Brief Summary Text (32):

The third component of the teeth whitening system is a polishing paste that includes a white pigmenting agent. This compound is formulated into a paste or cream that can be placed on a toothbrush and brushed onto the teeth. The polishing agent utilized in this compound is a dental abrasive that can debride and physically scrub the external surface of teeth. This scrubbing action removes filmy bacterial and plaque layers as well as some of the stains and discoloring pigments that are found on teeth that cause the undesired discoloration. These polishing agents also microabrade the tooth so as to polish the teeth to give the enamel a more lustrous appearance and a higher optical sheen. This microabrasion action enhances the scrubbed teeth's ability to reflect white light and thereby appear brighter.

Brief Summary Text (34):

The pigmenting agent that is included in the formulation of the polishing and pigmented cream or paste is titanium dioxide. This pigmenting agent is particularly useful because of its brilliant opaque white color and its extremely small particle size. Other pigmenting agents with these qualities would be equally applicable and useful to this invention. A further benefit of titanium dioxide as the pigmenting agent is its ability to also function as a polishing or abrading agent when it is being applied. This further enhances the polishing features of the complete compound. Titanium dioxide particles that are useful in the present formulation have an approximate size of between 0.1-1.5 microns and most preferably have a particle size between 0.1-0.2 microns. A pigmenting agent having this approximate size allows the pigmenting agent to be absorbed by the enamel of the teeth and occupy the space between the hydroxyapatite crystals or prisms that make up the enamel layer of the teeth. Thus, this pigment competes with the substances that tend to stain or discolor teeth by filling the space between the prisms with a white pigment instead of an undesired color pigment. This has the ultimate effect of "staining" the teeth white by absorption or masking of other discolorations.

Brief Summary Text (42):

In use, approximately 1-5 g of the polishing and pigmented cream is applied to a toothbrush and brushed vigorously onto the teeth. Brushing is continued for 1-3 minutes and is occasioned by a brilliant white lather that is generated by proper brushing and that should be maintained for the entire brushing sequence. The cream should be allowed to remain on the teeth for as long as possible, preferably overnight. This cream further abrades the pellicle film on the enamel while also polishing the enamel to create a lustrous sheen on the teeth. The pigment is absorbed into the enamel prisms and "stains" the enamel a more brilliant white and masks already present discolorations in and on the enamel layer of the teeth. This part of the teeth whitening system follows the application of the two previous substances, but could also be used alone.

Brief Summary Text (43):

In accordance with the present invention, the complete teeth whitening system, including the mouth rinse, bleaching gel and polishing and pigmented cream, are to be used on a daily basis with a noticeable whitening of the user's teeth within a short period of time following regular use. It is also envisioned that the bleaching gel and the polishing and pigmented cream be used individually or in combination with each other, apart from their use in the complete teeth whitening system.

Detailed Description Text (5):

A sufficient quantity of the mouth rinse is placed in the user's mouth and is caused to come in contact with the user's teeth by normal methods employed in mouth rinses.

Detailed Description Text (6):

Use of this mouth rinse cleanses the teeth of some of the accumulated pellicle film that builds up on human teeth and that commonly contains discoloring or stain causing substances.

Detailed Description Text (10):

This bleaching compound is a viscous gel and is to be placed on an applicator or cotton swab for applying the gel onto the teeth. Approximately 1-5 grams of the gel is to be applied to the applicator and allowed to remain on the teeth for 3 minutes. This compound gently bleaches the teeth enamel and removes some of the discoloring stains and pigments.

Detailed Description Text (13):

A sufficient quantity of a reagent referred to as stock solution A is first prepared. On a weight/volume basis, 300 grams of deionized water is combined with 135 grams of a 70% aqueous solution of Sorbitol and 900 grams of glycerin. This solution is mixed and stirred for 1 hour and then 1.5 grams of sodium lauryl sulfate, 3.0 grams of sodium saccharine, 7.0 grams of methyl salicylate and 2.8 grams of menthol flavor crystals are added and stirred for an additional 30 minutes. The resulting clear liquid is stock solution A.

Detailed Description Text (15):

This cream is then placed on a toothbrush and is brushed and burnished onto the user's teeth. Approximately 1-5 grams of the cream is placed on the brush and is brushed on the teeth for 3 minutes. The brushing is occasioned by a brilliant white lather that is maintained throughout the brushing period. The cream is then rinsed away with water leaving the teeth with a bright, white appearance and a lustrous sheen after regular use.

Other Reference Publication (2):

Endodontics and Dental Traumatology, vol. 4, No. 1, 1988, "Incidence of External Root Resorption and Esthetic Results in 58 Bleached Pulpless Teeth" (S. Friedman, et al.), pp. 23-26.

Other Reference Publication (3):

Pediatric Dentistry, vol. 7, No. 3, 1985, "Color Change Following Vital Bleaching of Tetracycline--stained Teeth" (Carolyn Wilson, et al.), pp. 205-208.

Other Reference Publication (4):

J. Dental Research, vol. 60, No. 5, May 1981, "Pulpal Reaction to Bleaching of Teeth

in Dogs" (Seale, et al.), pp. 948-953.

CLAIMS:

1. A three component system for whitening human teeth wherein each component is applied to the teeth in a sequential manner, said three component system comprising:

a first component comprising a conditioning mouth rinse capable of cleansing the surface of said teeth;

a second component comprising a viscous bleaching gel including an effective concentration of hydrogen peroxide for bleaching said teeth, said hydrogen peroxide present in an amount ranging from 1 to 10% by weight of the total gel; and

a third component comprising a viscous polishing composition including an abrasive substance for polishing said teeth and a pigmenting agent capable of imparting a white color to said teeth, whereby said conditioning rinse, said bleaching gel and said polishing composition are applied individually and seriatim to said teeth.

6. The system as set forth in claim 1 wherein said effective concentration of said hydrogen peroxide in said gel is between 3 percent and 8 percent.

7. The system as set forth in claim 6 wherein said concentration of said hydrogen peroxide is 6 percent.

WEST

L9: Entry 11 of 15

File: USPT

Jun 16, 1992

DOCUMENT-IDENTIFIER: US 5122365 A

TITLE: Teeth whitenerAbstract Text (1):

A three component system and method for whitening teeth that comprises four primary active ingredients. The first component is a pre-conditioning mouth rinse comprised of a dilute aqueous solution of acetic acid and flavor enhancing additives. This component cleanses the pellicle film on the user's teeth. The second component is a bleaching gel including hydrogen peroxide. This gel also includes flavor enhancers, preservatives or surfactants necessary to formulate the gel. The preferred concentration of hydrogen peroxide is about six percent. The third component of the teeth whitening system is a polishing and pigmenting cream or paste that includes an abrasive substance and a pigmenting agent. The abrasive agent is preferably an alumina silicate and the pigmenting agent is preferably titanium dioxide particles. Flavor enhancers, a carrier, thickening agents, surfactants, preservatives and water are also to formulate the cream or paste. Methods of use formulation of the products are included.

Brief Summary Text (1):

This invention relates in general to teeth whitening dentrifrices and more particularly to a new system containing a plurality of substances used in combination that is useful for whitening and polishing human teeth.

Brief Summary Text (2):

For a variety of reasons it has become desirable for a person's teeth to appear bright or "white". Society places a high value on the "whiteness" of one's teeth. One whose teeth are white may enjoy more personal confidence and satisfaction and may even enjoy greater social acceptance. In many business situations, such as acting and television newsreporting, a person's appearance is of the utmost importance in securing employment and having "white" teeth is known to be an asset.

Brief Summary Text (3):

A tooth is comprised of an inner dentin layer and an outer hard enamel layer that is the protective layer of the tooth. The enamel layer of a tooth is naturally an opaque white or slightly off-white color. It is this enamel layer that can become stained or discolored. The enamel layer of a tooth is composed of hydroxyapatite mineral crystals that create a somewhat porous surface. These hydroxyapatite crystals form microscopic hexagonal rods or prisms that make up the enamel surface. As a result, the surface of the enamel layer presents microscopic spaces or pores between the prisms. It is believed that this porous nature of the enamel layer is that allows staining agents and discoloring substances to permeate the enamel and discolor the tooth. These remaining substances can occupy the microscopic spaces and eventually alter the color of the tooth.

Brief Summary Text (4):

Many substances that a person confronts or comes in contact with on a daily basis can "stain" or reduce the "whiteness" of one's teeth. In particular, the foods, tobacco products and fluids that one consumes tend to stain one's teeth. These products or substances tend to accumulate on the enamel layer of the tooth and form a pellicle film over the teeth. These staining and discoloring substances can then permeate the enamel layer. This problem occurs gradually over many years, but imparts a noticeable discoloration of the enamel of one's teeth. Some diseases and environmental factors may also have the effect of discoloring one's teeth. So long

as the discolored teeth are still healthy and do not pose any health risk or problem, a product or substance that would whiten the discolored teeth would be advantageous.

Brief Summary Text (5):

It is also essential that a teeth whitening product that is to be used at home or in private by the consumer be safe and easy to use. A product for home use cannot utilize some of the compositions or products for whitening teeth that are available for use by a trained dental professional. For example, a 35% hydrogen peroxide bleaching agent is utilized by many dental practitioners to bleach severely discolored teeth. Such a concentrated solution of hydrogen peroxide would be irritating and potentially dangerous for home use by the consumer. Products and substances that are presently available to whiten teeth include a variety of different ingredients, but the primary active ingredient is an abrasive agent formulated into a gel or paste. These abrasive gel type products "polish" the enamel layer of the teeth to which it is applied and give it a more lustrous sheen and partially scrub away materials that stain the tooth enamel. These abrasive products are not able to perform all of the desired functions in a fully satisfactory manner.

Brief Summary Text (6):

It is therefore a primary object of the present invention to provide a system for whitening teeth that is more effective in whitening teeth and safer to use than existing products available to the consumer.

Brief Summary Text (7):

It is another object of the present invention to provide a system for whitening teeth that includes a cleansing mouth rinse, a bleaching substance and a pigmenting agent as well as an abrading and polishing agent to more completely and more efficiently whiten teeth than known products.

Brief Summary Text (8):

It is still another objects of the present invention to provide a complete system for whitening the enamel of human teeth that is safe for home use and a method of use that can easily be performed by the consumer without the assistance of a trained dental professional.

Brief Summary Text (9):

It is a further object of the present invention to provide a system and method for whitening human teeth where the component parts of the system are to be used in a sequential manner to cosmetically whiten a person's teeth.

Brief Summary Text (10):

It is a still further object of the present invention to provide a teeth whitening product that includes an effective quantity of a bleaching agent such as hydrogen peroxide in a concentration that can be safely and comfortably used at home by the consumer.

Brief Summary Text (11):

It is yet a further object of the present invention to provide a product for whitening teeth that includes an effective quantity of hydrogen peroxide to bleach teeth in a manageable and convenient gel medium that can be applied with the use of an appropriate applicator.

Brief Summary Text (12):

It is an aim of the present invention to provide a product for whitening teeth that includes a pigmenting substance that is of a small enough particle size to fit into the pores or spaces between the hydryxyapatte crystals of enamel prisms that make up the enamel layer.

Brief Summary Text (13):

It is another aim of the present invention to provide a teeth whitening product that utilizes a pigmenting substance that imparts a white pigment to the enamel layer of the tooth and that also functions as an abrasive substance to polish the teeth.

Brief Summary Text (14):

It is a further aim of the present invention to provide a system for whitening teeth that can safely and effectively be used on a daily basis to prevent further discoloration of the user's teeth.

Brief Summary Text (16):

The present invention is directed to an improved system and method for whitening teeth that has three separately formulated components having four primary active ingredients to serve as a complete and effective teeth whitener. In accordance with the invention, the first component is a teeth cleansing mouth rinse formulated by preparing a dilute, aqueous solution of acetic acid in combination with flavor enhancers, a preservative, a surfactant and mixtures thereof. The second component of the system is a gel capable of bleaching teeth enamel and is formulated as a combination of hydrogen peroxide, a gelling agent capable of maintaining the stability of the hydrogen peroxide over a period of time, a neutralizing agent, a thickening agent and mixtures thereof. The third component of the teeth whitening system and method is a polishing cream or paste that includes a pigmenting agent. The polishing cream is formulated by combining deionized water, a carrier, an abrasive polishing agent, flavor enhancers, thickening agents, surfactants, a pigmenting agent and mixtures thereof. Alumina silicates are most useful as the abrasive and polishing agent and most preferred are synthetic precipitated amorphous alumina silicates sold under the trademarks ZEO-49 or ZEODENT 113 by the J. M. Huber Corp. of Havre de Grace, Md. The preferred carrier is glycerin and the most preferred pigmenting agent is titanium dioxide.

Brief Summary Text (18):

The components of the present teeth whitening system are to be used in a sequential fashion. The user first rinses his mouth and concomitantly his teeth with the conditioning mouth rinse of the invention. This is followed by applying the bleaching gel onto the teeth. This second component is applied onto the teeth for approximately 1-4 minutes and then the teeth are rinsed with water. Finally, the polishing and pigmented cream is brushed onto the teeth. This component of the system is brushed onto the teeth for about 1-3 minutes and left on the teeth as long as possible, preferably overnight.

Brief Summary Text (20):

In accordance with the invention, a three component teeth whitening system is provided. Each component is formulated and packaged separately. In formulating the components, pharmaceutical grade reagents, if available, should be used throughout and all necessary safety and sterility procedures should be employed for a product that will be used in contact with human teeth and oral tissues.

Brief Summary Text (21):

The first component of the teeth whitening system is a conditioning mouth rinse. This mouth rinse is comprised generally of an aqueous dilution of acetic acid. The preferred concentration range of the acetic acid in the solution is between 1%-3% and is most preferably between 0.5%-1.5% acetic acid. Normal white distilled or household vinegar can be used to prepare the mouth rinse.

Brief Summary Text (25):

In preparing the conditioning mouth rinse, deionized water is first heated to about 80.degree. C. and any preservative or sweetener is dissolved therein. The solution is then allowed to cool and an appropriate amount of 5% acetic acid is added to obtain the desired final concentration. At this point, a surfactant is added and any flavoring chemical or composition is likewise added. The resulting solution is stirred until all of the substances are fully dissolved. The rinse is now ready for its use in cleansing and debriding the pellicle film that accumulates on the enamel of teeth. The application of this rinse to a person's teeth pre-conditions the enamel layer of the teeth to be more accessible to the actions of the subsequent components of the whitening system.

Brief Summary Text (26):

The second component of the teeth whitening system of the present invention is a bleaching gel. The active ingredient in this bleaching component is hydrogen peroxide. This component of the whitening system uses a relatively low concentration

of hydrogen peroxide in a gel form. A high concentration of hydrogen peroxide could not be used safely by the typical consumer and therefore the useful range of hydrogen peroxide in the gel is between 1%-10% hydrogen (by weight). The most preferred range is between 3%-6.5% and the most preferred concentration is 6% in the gel. Hydrogen peroxide generally has a pH of between 3-6 and is preferably maintained about 6. The hydrogen peroxide is prepared as a gel to provide a safe and easy form in which it may be applied onto the user's teeth. A liquid hydrogen peroxide formulation would be irritating to the gums and gingival tissues and would therefore not be as useful as the preferred easy to use gel form in accordance with the instant invention.

Brief Summary Text (29):

The most preferred gelling agent is a water dispersible copolymer of acrylic acid cross-linked with approximately 0.75% to approximately 1.5% polyallyl sucrose that is sold under the trademark CARBOPOL 934 by B. F. Goodrich. This gelling agent is neutralized with triethanolamine or another suitable alkalinizing agent as discussed in U.S. Pat. No. 3,499,844 to achieve a pH of the final product around 3.5. In order to obtain the most useful gel for use in the present invention a sufficient amount of non-ionic cellulose or gum is added to the gel to improve the physical stability of the gel. This is basically a thickening agent and hydroxyethylcellulose gum, hydroxypropylcellulose gum or carboxymethyl cellulose work effectively and are preferred, although other like products would have utility.

Brief Summary Text (30):

In preparation, the bleaching gel that is the second component of the teeth whitening system preferably comprises 6% by weight of hydrogen peroxide, 2% of CARBOPOL 934 (an acrylic acid copolymer cross-linked with polyallyl sucrose), 1% of triethanolamine, 1% by weight of hydroxyethylcellulose, and the remainder is deionized water. This formulation is prepared by first combining an appropriate amount of a 35% aqueous solution of hydrogen peroxide with deionized water. This mixture is slowly stirred and CARBOPOL 934 is gradually added. After the gelling agent has become thoroughly dispersed in the hydrogen peroxide solution, the hydroxyethylcellulose is slowly added until it dissolves. Finally, 99% triethanolamine is diluted in a 1:1 ratio with deionized water and slowly added to the gelled solution to achieve a final pH of approximately 3.5. The resulting compound is a clear, homogenous, stable and viscous gel.

Brief Summary Text (31):

The bleaching gel can then be placed on an applicator such as a cotton swab and applied onto the teeth for 1-4 minutes. Alternatively, the bleaching gel may be applied directly to the teeth and allowed to remain in contact therewith for a like amount of time. The gel is then removed by rinsing with water.

Brief Summary Text (32):

The third component of the teeth whitening system is a polishing paste that includes a white pigmenting agent. This compound is formulated into a paste or cream that can be placed on a toothbrush and brushed onto the teeth. The polishing agent utilized in this compound is a dental abrasive that can debride and physically scrub the external surface of teeth. This scrubbing action removes filmy bacterial and plaque layers as well as some of the stains and discoloring pigments that are found on teeth that cause the undesired discoloration. These polishing agents also microabrade the tooth so as to polish the teeth to give the enamel a more lustrous appearance and a higher optical sheen. This microabrasion action enhances the scrubbed teeth's ability to reflect white light and thereby appear brighter.

Brief Summary Text (34):

The pigmenting agent that is included in the formulation of the polishing and pigmented cream or paste is titanium dioxide. This pigmenting agent is particularly useful because of its brilliant opaque white color and its extremely small particle size. Other pigmenting agents with these qualities would be equally applicable and useful to this invention. A further benefit of titanium dioxide as the pigmenting agent is its ability to also function as a polishing or abrading agent when it is being applied. This further enhances the polishing features of the complete compound. Titanium dioxide particles that are useful in the present formulation have an approximate size of between 0.1-1.5 microns and most preferably have a particle size between 0.1-0.2 microns. A pigmenting agent having this approximate size allows

the pigmenting agent to be absorbed by the enamel of the teeth and occupy the space between the hydroxyapatite crystals or prisms that make up the enamel layer of the teeth. Thus, this pigment competes with the substances that tend to stain or discolor teeth by filling the space between the prisms with a white pigment instead of an undesired color pigment. This has the ultimate effect of "staining" the teeth white by absorption or masking of other discolorations.

Brief Summary Text (42) :

In use, approximately 1-5 g of the polishing and pigmented cream is applied to a toothbrush and brushed vigorously onto the teeth. Brushing is continued for 1-3 minutes and is occasioned by a brilliant white lather that is generated by proper brushing and that should be maintained for the entire brushing sequence. The cream should be allowed to remain on the teeth for as long as possible, preferably overnight. This cream further abrades the pellicle film on the enamel while also polishing the enamel to create a lustrous sheen on the teeth. The pigment is absorbed into the enamel prisms and "stains" the enamel a more brilliant white and masks already present discolorations in and on the enamel layer of the teeth. This part of the teeth whitening system follows the application of the two previous substances, but could also be used alone.

Brief Summary Text (43) :

In accordance with the present invention, the complete teeth whitening system, including the mouth rinse, bleaching gel and polishing and pigmented cream, are to be used on a daily basis with a noticeable whitening of the user's teeth within a short period of time following regular use. It is also envisioned that the bleaching gel and the polishing and pigmented cream be used individually or in combination with each other, apart from their use in the complete teeth whitening system.

Detailed Description Text (5) :

A sufficient quantity of the mouth rinse is placed in the user's mouth and is caused to come in contact with the user's teeth by normal methods employed in mouth rinses.

Detailed Description Text (6) :

Use of this mouth rinse cleanses the teeth of some of the accumulated pellicle film that builds up on human teeth and that commonly contains discoloring or stain causing substances.

Detailed Description Text (10) :

This bleaching compound is a viscous gel and is to be placed on an applicator or cotton swab for applying the gel onto the teeth. Approximately 1-5 grams of the gel is to be applied to the applicator and allowed to remain on the teeth for 3 minutes. This compound gently bleaches the teeth enamel and removes some of the discoloring stains and pigments.

Detailed Description Text (13) :

A sufficient quantity of a reagent referred to as stock solution A is first prepared. On a weight/volume basis, 300 grams of deionized water is combined with 135 grams of a 70% aqueous solution of Sorbitol and 900 grams of glycerin. This solution is mixed and stirred for 1 hour and then 1.5 grams of sodium lauryl sulfate, 3.0 grams of sodium saccharine, 7.0 grams of methyl salicylate and 2.8 grams of menthol flavor crystals are added and stirred for an additional 30 minutes. The resulting clear liquid is stock solution A.

Detailed Description Text (15) :

This cream is then placed on a toothbrush and is brushed and burnished onto the user's teeth. Approximately 1-5 grams of the cream is placed on the brush and is brushed on the teeth for 3 minutes. The brushing is occasioned by a brilliant white lather that is maintained throughout the brushing period. The cream is then rinsed away with water leaving the teeth with a bright, white appearance and a lustrous sheen after regular use.

Other Reference Publication (2) :

Endodontics and Dental Traumatology, vol. 4, No. 1, 1988, "Incidence of External Root Resorption and Esthetic Results in 58 Bleached Pulpless Teeth" (S. Friedman, et

al.), pp. 23-26.

Other Reference Publication (3):

Pediatric Dentistry, vol. 7, No. 3, 1985, "Color Change Following Vital Bleaching of Tetracycline-stained Teeth" (Carolyn Wilson, et al.), pp. 205-208.

CLAIMS:

1. A three component package for whitening human teeth wherein each component is applied to the teeth in a sequential manner, said three component package comprising:

a first component comprising a conditioning mouth rinse capable of cleansing the surface of said teeth, said mouth rinse comprising an aqueous solution of acetic acid; and

a second component comprising a viscous bleaching gel including an effective concentration of hydrogen peroxide for bleaching said teeth, said hydrogen peroxide present in an amount ranging from 1 to 10% by weight of the total gel; and

a third component comprising a viscous polishing composition including an abrasive substance comprising alumina silicates for polishing said teeth and a pigmenting agent capable of imparting a white color to said teeth, whereby said conditioning rinse, said bleaching gel and said polishing composition are applied individually and seriatim to said teeth.

6. The package as set forth in claim 1 wherein said effective concentration of said hydrogen peroxide in said gel is between 3 percent and 8 percent.

7. The package as set forth in claim 6 wherein said concentration of said hydrogen peroxide is 6 percent.